ISSUES IN TREATMENT ASSESSMENT

National Institute of Mental Health

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BIOFEEDBACK–

ISSUES IN TREATMENT ASSESSMENT

ON THE COVER

Rippled Surface
M.C. Escher

National Gallery of Art
Washington, D.C.
Gift of Mr. C.V.S. Roosevelt

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ISSUES IN TREATMENT ASSESSMENT

By Bette Runck
Staff Science Writer, NIMH

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Alcohol, Drug Abuse, and Mental Health Administration

National Institute of Mental Health
5600 Fishers Lane
Rockville, Maryland 20857

In Memoriam

EUNICE CORFMAN

1928-1980

Eunice Corfman brought surpassing intelligence, energy, and devotion to her role as Editor-in-Chief of the NIMH Science Monograph/Report series. This volume, stimulated by her leadership, is dedicated to her memory. The first in a new subseries of reports on treatment assessment, it reflects several of Eunice's key concerns: the many ways of knowing; the interaction of body and mind in the service of health; the search for excellence; and the humane uses of reason.

Though this extraordinary person is no longer with us, her goals and values remain—particularly her commitment to communicating the excitement and significance of scientific research.

The Staff
Science Reports Branch
Division of Scientific and Public Information
National Institute of Mental Health

FOREWORD

As one expression of growing public concern with the cost and quality of physical and mental health care in the United States, increasing attention is being given to the technologies of treatment and prevention. We are searching for safe, less expensive, and effective ways to prevent disease and disorder while seeking to alter their course and adverse consequences. At the same time we are attempting to improve the rigor of our techniques for judging the merits of existing and developing health technologies.

A number of additional substantive issues color the ways we currently view health and illness. Of particular importance is our enhanced appreciation of the continual and reciprocal interaction of biological and psychosocial factors, which together influence the maintenance of health, the onset and course of disease, the impact of treatment, and, ultimately, the longevity and well-being of the population at large.

In response to issues of both clinical practice and scientific investigation, the National Institute of Mental Health (NIMH) is taking an increasingly active role in stimulating the rigorous assessment of current and emerging techniques for treating mental disorder and in catalyzing further study of the role of psychosocial factors in the etiology, prevention, and treatment of selected physical disorders. It is, therefore, particularly appropriate that the NIMH Science Reports Branch devote a number of its Science Reports specifically to treatment assessment. The new subseries is designed to provide current information on selected psychological and physical treatments for a relatively broad and diversified audience of scientists and lay people. It is fortunate, indeed, to begin with biofeedback, a technique of considerable interest for the treatment of disorders which typically find expression in physical symptoms but which are unusually influenced by psychological stress.

Reports in this series neither endorse nor reject specific treatment techniques. Nor do they represent official NIMH

"position" papers. Rather, these reports explore current issues, thoughts, and evidence gleaned from major researchers in the substantive treatment areas under discussion. Those searching for simple answers to complex questions of treatment assessment are unlikely to find them in this group of reports. However, they may discover why such answers are so hard to come by. This volume, like others in the series, should improve the level of dialogue among researchers, policymakers, and clinical practitioners. It may also provide consumers with a better understanding of what to expect from the diverse—and sometimes controversial—treatment applications of biofeedback.

Herbert Pardes, M.D.
Director
National Institute of Mental Health

PREFACE

During the past 20-plus years of support by the National Institute of Mental Health for biofeedback studies, the field has grown dramatically. A relatively obscure laboratory tool for exploring autonomic control has blossomed into a well-known and widely used treatment for mental and physical disorders. During the same period consumers have grown more wary, policymakers more rationalistic, and researchers more capable of providing the kinds of sophisticated assessments of treatments demanded by an increasingly tough-minded and tightfisted age. Despite great progress in understanding, refining, and applying biofeedback technology, many skeptics still find sufficient grounds for questioning whether the efficacy of biofeedback warrants its broad use.

There are at least two kinds of skeptics: uninformed and informed. The uninformed know little about the technique or its evaluation but have an instinctive distrust of a "treatment" that involves no medicine and appears to depend more on the patient's own efforts than on those of the therapist. Equally disturbing to them is the use of a mechanical apparatus (shades of 19th-century electromagnetic quackery) and the peculiar marriage of mind and machine inherent in the technique—a Western caricature of Eastern meditation.

The informed skeptics, many of them biofeedback researchers, demand of themselves and their scientific colleagues the highest standards of proof of efficacy. They will not rest content with innumerable favorable reports of biofeedback treatment applications unless they know the studies were designed to rule out extraneous sources of apparent success.

In this respect, it is important to note, as did Neal Miller in reviewing this report:

> Except for drugs, surprisingly few of the therapeutic techniques widely used by physicians have been subjected to the rigorous type of evaluation cor-

> rectly called for in the case of biofeedback. Furthermore, in a number of cases where traditionally used medical techniques have been evaluated rigorously, the results have been negative.

Or, as Gary Schwartz has noted:

> Biofeedback is unique among all the behavioral-medical disciplines in being absolutely committed to modification of itself and its methods in response to feedback regarding . . . effectiveness in the real world.

Accordingly, this report, which represents a compilation of many sophisticated assessments of the biofeedback evidence, should be read with an appreciation of the unusually exacting standards to which these researchers hold themselves.

Another critical message, written between the lines, concerns the capacity to see the world in shades of grey. Currently there are considerable pressures on the scientific community to develop definitive statements for policymakers about a variety of treatments—indicating whether particular treatments "work" and whether their effectiveness justifies their costs. To the unending consternation of many decisionmakers, who prefer clear yes-or-no answers, the scientific community often responds to such questions with answers like "it depends," or, even more maddeningly, with more questions. Those who read this report with care are likely to understand better the logic of rigorous treatment assessment and the rationale for the researcher's eternal caution and circumspection. They may come away skeptics, but they will be informed skeptics.

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1

BEGINNING BIOFEEDBACK

Around the turn of the century, a psychologist named J.H. Bair trained several young men to wiggle their ears. Now, this was no idle prank devised by the professor to endear himself to students. Bair was trying to understand how a person develops voluntary control over muscle movement.

This was Bair's procedure: First, the men gave themselves a very mild shock by pressing a key that was wired to stimulating electrodes attached to their ears. The shock jolted their ears into contracting (the ears, in other words, wiggled). Next, the men tried to move their ears without electrical help. By clenching their jaws and knitting their brows they found they could make their ears move too. They could detect this faint sensation—normally lost amid the noisy muscles of cheek, chin, and brow—because they remembered how electrically induced ear contractions felt. They kept practicing, concentrating their attention on the sensation in their ears. Slowly they learned to dispense with the jaw-clenching and brow-knitting until finally they had perfected the rare, if useless, skill of wiggling their ears.

Modern biofeedback training has much in common with Bair's technique. Like ear-wiggling, the skills learned in a biofeedback clinic involve functions and responses that are usually outside the patient's ability to control—blood pressure and circulation, for example, or a tight, spastic, or paralyzed muscle. These normally inconspicuous responses become detectable because they are monitored, amplified, recorded, and fed back to the patient by a mechanical or electronic device. Biofeedback patients can, in effect, "watch" or "hear" fluctuations in their blood pressure or heartbeat or in the activity of a single muscle cell. Then, using a variety of maneuvers that are already voluntary, the patient may learn to control the formerly involuntary response, just as Bair's subjects used brow-knitting as a way to learn ear-wiggling.

Bair's experiment, reported in a 1901 issue of the journal, *Psychological Review,* demonstrated that to control a response a person must first be able to sense it. The importance of feedback to this and other kinds of control had long been known, but two of Bair's contemporaries had formally demonstrated it a few years earlier. British scientists F.W. Mott and C.S. Sherrington (1895) severed the afferent nerves of a monkey's forelimb. These nerves are part of the body's own feedback channels, which carry information about the limb's activity back to the central integrating portions of the nervous system. Mott and Sherrington observed that, when deprived of this afferent feedback, the monkey could no longer use the limb voluntarily.* But, as a practical matter, the importance of feedback was not discovered in that 19th-century laboratory. For centuries, monitoring performance has eased the learning of complex skills in gymnasium, clinic, home, field, and shop.

In the middle of the 20th century the "information feedback principle" was explicitly recognized in a new discipline, cybernetics. Systems theorists demonstrated how information about a system's past performance—that is, feedback—enhances the accuracy and precision of future performances.

*Recent work by psychophysiologist Edward Taub shows that the loss of control is far from complete.

In the late fifties and early sixties, investigators began using the feedback principle to try to alter biological systems. Perhaps cashing in on the fashionability of cybernetics, they borrowed the new discipline's terminology and coined the word "biofeedback." As one of the field's pioneers, John V. Basmajian, has observed (1979), biofeedback is an artificial name "that some scientists and clinicians abhor for linguistic and other reasons." Among its other deficiencies, the word biofeedback has come to imply that people can intentionally regulate their own finely tuned inner workings just as they control machines. This illusion may have been partly responsible for the turbulence of the field's short history.

Biofeedback is a far more complex procedure than it would appear to be at first glance. Moment by moment, the human body regulates itself with feedback through mechanisms so complex that scientists have only recently begun to appreciate how little we understand about what goes on under our own skins. The alterations attempted with biofeedback techniques are, compared to the body's own intricate and sophisticated capabilities, gross and naive. As it turns out, the mechanisms through which the techniques work probably vary from one application to another. Sometimes, the type of learning used by Bair's subjects to wiggle their ears may be involved in the acquisition of skills. But many biofeedback applications seem to be little more than shortcuts to relaxation.

A Patient in a Biofeedback Clinic

In a typical case, a man with recurrent tension headaches goes in for biofeedback training to learn to relax the tight muscles in his head and neck. He is led into a small, soundproof, dimly lit room and asked to recline on a couch. A therapist attaches three recording electrodes to his forehead—one about an inch above each eyebrow, another in the center. Wires lead from the electrodes to an electromyograph, a machine that measures and records electrical potential in the muscles—what is commonly considered the degree of tension. Bioelectrical charges are conveyed from the electrodes

to the machine, which amplifies and converts them to a feedback signal—in this case, a click. The therapist explains that the tighter the muscles, the faster the clicks will come. The headache victim, by listening to the clicks, learns to recognize which feelings and thoughts make the machine click faster. His job is to discover what it feels like to relax his muscles, to notice how he feels when he makes the clicks slow down. Then he tries to maintain that state. If the training sessions work, he gradually learns to reproduce the state of relaxation without need of the clicking machine.

Tension headaches are just one of several conditions that have been treated with biofeedback techniques in the few years since biofeedback was baptized as a promising tool for controlling physiological responses. Since the early sixties, investigators have used a variety of devices to teach patients and experimental subjects to control not only muscular activity but heart rate, blood pressure, and other visceral processes once thought to be involuntary. The excitement engendered by that early work, particularly reports that human subjects could learn to produce brainwaves associated with a state of well-being, reached the point at which the public was being urged "to enjoy a euphoric ride on the crest of a wave of therapeutic ebullience that sometimes borders on mindless omnipotence" (Birk 1973). Accounts in the popular press were hardly more extravagant in their claims than those made in academic and clinical journals.

The Early Years

Biofeedback developed during a time when the machine was used as a metaphor for the body, with the computer an analog for its control center, the brain. The times and the terminology fostered a belief that the mysteries of the human organism could be understood and controlled mechanistically. The early experiments with brainwave biofeedback, ballyhooed as a quick-and-easy pathway to nirvana, fed the illusion. The fact that biofeedback represented a marriage of machine and person—a system so intimately entwined that "live" wires connected the two—provided an irresistible en-

ticement to overly optimistic claims for the wonders of the technique.

Biofeedback originated in the work of investigators from several different disciplines that began to converge in the late 1960s. Each source has influenced the field in its own way.

The first, perhaps the oldest, was the use of electromyography (EMG) to rehabilitate patients who had suffered neuromuscular injury, and even partial paralysis, as the result of strokes, accidents, or diseases such as cerebral palsy. The EMG, which measures electrical signals from muscle fiber, had been used for decades. Then, early in the 1960s, investigators began using myoelectrical signals (transformed into visual or auditory stimuli) to train patients to regain at least partial control of damaged neuromuscular units. John V. Basmajian at McMaster University in Canada demonstrated that normal subjects could consciously isolate and activate single motor units, which led him and other investigators (e.g., Stoyva 1976a and b, and Budzynski et al. 1973) to develop techniques for controlling muscle tension. The EMG has since become the clinical "workhorse" of biofeedback (Stoyva 1979). It is usually used to teach patients to reduce the tension that is thought to contribute to many chronic health problems.

A second source of biofeedback—recognizing and perhaps controlling brain activity—caught the popular imagination in the late 1960s and gave the whole field great commercial impetus. Working independently, Joe Kamiya (1969) at the University of Chicago and Barbara Brown (1970) at the Sepulveda, Calif., Veterans Administration Hospital were teaching patients to produce a particular brainwave frequency called "alpha." With recording electrodes attached to their skulls producing an electroencephalographic (EEG) record, subjects could "watch" their own brainwaves, and apparently produce, on demand, the feeling states associated with particular brainwave patterns. Producing the alpha pattern, which the subjects reported to be associated with a relaxed but alert state, became the goal of most of this work.

Another group of experiments on human subjects, started even earlier than the EEG research, involved attempts to use

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operant conditioning techniques to alter responses controlled by the autonomic nervous system. Much of this early work focused on the galvanic skin response (GSR), a measure of the electrical conductivity of the skin—a property which, in turn, is related to the degree of emotional arousal. H. D. Kimmel, whose experiments at the University of Florida were among the first of this type, has traced the development of attempts to condition the GSR and heart rate through rewards and punishments (Kimmel 1974). According to him, the earliest work, done in the Soviet Union, Canada, and the United States, was followed by research at several different laboratories which confirmed that operant conditioning could produce changes in the GSR (e.g., see Razran 1961 and Shapiro et al. 1964). Attention then turned to whether the changes were "pure" or were merely side effects of the subjects' learning to control such responses as muscle tension (e.g., Birk et al. 1966).

Animal studies begun at about the same time also addressed the question of mediating events that might account for the observed changes. The work of one group of investigators, in particular, made scientists sit up and take notice of research using feedback techniques. The eminent psychologist, Neal Miller, and his associates at Yale and Rockefeller Universities conducted a series of highly influential experiments demonstrating that paralyzed rats could be trained to change visceral responses in whatever direction the investigators chose. Some rats, for example, were trained to raise or lower their blood pressure or heart rates. Some were conditioned to warm one ear and make it blush while the other ear stayed its normal temperature and color.

Just as the work of Brown and Kamiya attracted the attention of the press and public, the early experiments of Miller and his colleagues focused scientific attention on the possibility that physiological processes were much more amenable to learning than had been thought. Researchers began to probe deeper and deeper. The promise of biofeedback as a clinical tool was matched by its potential as a method for understanding the interaction of physical and psychological processes. While trying to understand how human and animal subjects

control physiological responses, investigators have come to a deeper appreciation of the profoundly complex interdependence of body and mind.

In the decade or so since biofeedback caught on as a technique for treating stress-related disorders, hundreds of articles on the subject have appeared in the professional literature. Most are based on clinical experience with a few cases. Patients with migraine headaches have learned to warm their fingers, which somehow relieves their pain. Those with a sometimes-severe disorder of circulation called "Raynaud's disease," which is characterized by painfully cold hands, have also learned to raise the temperature in their extremities. EMG feedback has been used to reduce tension in patients with muscle-contraction headaches, abnormal heart conditions, and neuromuscular disorders. Some patients with epilepsy have managed to control seizures through EEG feedback training. An early application of feedback training, to control bedwetting, continues to be used. Further, normal subjects, usually college students easily accessible to researchers, have also been trained to alter blood pressure, heart rate, and other physiological processes.

Despite the positive results reported in these articles, biofeedback as a clinical technique remains unproven. Careful reviews of the evidence, the reviews on which the bulk of this report is based, have been critical of the methods used to evaluate the clinical value of biofeedback. For example, most clinical studies have failed to take into account long-recognized *nonspecific* effects that result from treatment of *any* kind. Even drugs cannot be evaluated without taking nonspecific or placebo effects into account. A whole variety of circumstances, not the least of which is the concerned attention of a therapist, can help a patient get better, whether the disorder is as biologically based as a cancer or as psychologically influenced as a depression.

Inadequate consideration of the factors contributing to the effectiveness of a treatment technique is only one failure of most research done to date on biofeedback. Another, perhaps even more important, issue concerns the ability of patients to transfer their new skills to everyday life. Can they be weaned

from the machines? Can the skill they learned over a period of weeks be maintained over a lifetime? Can they exert the same control when faced with stressful life situations that they could achieve in a darkened, quiet room surrounded by supportive therapists and technicians? Most of these questions have been addressed by one or more investigators, but seldom to the satisfaction of reviewers. Similarly, when controls have been used to discount the therapeutic contribution of placebo factors, other conditions render the results questionable.

Biofeedback as a State of Mind

Despite the equivocal findings of carefully controlled research on clinical uses of biofeedback, the field is alive and well. The Biofeedback Research Society, organized in 1970, has been expanded to reflect the widespread clinical uses of the technique and is now known as the Biofeedback Society of America (BSA). Since 1975, it has published a journal, *Biofeedback and Self-Regulation.* Many basic science studies are published in the journal, *Psychophysiology.* A collection of reprints, published in 1971, includes important articles published before 1970 (Kamiya et al. 1971). Later articles have been reprinted in an annual, published, with various editors, as *Biofeedback and Self-Control: An Aldine Annual on the Regulation of Bodily Processes and Consciousness* (1971-1979). A 1978 bibliography of the biofeedback literature (Butler) includes more than 2,300 citations.

Enthusiasm generated by the early reports of clinical and laboratory applications of biofeedback partly accounts for the recent shift in prevailing attitudes about responsibility for good health. Patients are no longer seen as passive receivers of health care. In the face of demonstrations that heart rate and blood pressure can be voluntarily altered, for example, many observers believe that hereditary predispositions toward certain diseases can be tempered through biofeedback training and other health-promoting activities.

This shift in attitudes has now been institutionalized under the rubric of *behavioral medicine*, complete with a journal (established in 1979) and a professional society, which held

its first meeting in December 1979. Heir to the concerns of psychosomatic medicine, behavioral medicine does not imply one or another theoretical point of view. The commonly accepted definition of the field evolved over several years. Its latest form was drafted by a group of researchers who met in April 1978 under the auspices of the Institute of Medicine of the National Academy of Sciences:

> Behavioral medicine is the *interdisciplinary* field concerned with the development and *integration* of behavioral *and* biomedical science knowledge and techniques relevant to health and illness and the application of this knowledge and these techniques to prevention, diagnosis, treatment and rehabilitation. [Schwartz and Weiss 1978, p. 250]

Schwartz and Weiss call attention to the fact that this definition does not describe traditional mental vs. physical disorders in "purely behavioral vs. biological terms." Rather, these disorders are "conceived and studied from a more integrated, *biobehavioral* perspective."

Biofeedback is one of several strategies within behavioral medicine for producing change. A related technique, training in self-management skills, is usually directed at modifying habits (such as overeating or smoking) rather than altering physiological responses. As in biofeedback, the patient or trainee takes responsibility for changing the behavior that contributes to health problems.*

Biofeedback and self-control training are not without their entrepreneurs. Both fields are regarded by some as tainted by commercialism. In our culture, we allow a taste for wealth in businessmen but expect health-care professionals to be made of finer stuff. Whether or not these techniques are socially approved, the research and popular literatures have been inundated with barely supportable claims to efficacy for them.

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*Research on self-management training is discussed in another report in this series.

Assessing Biofeedback

The crucial question today for biofeedback is not whether it can produce an effect. By now there have been ample demonstrations that at least some people can gain some control over many physiological functions. But whether these abilities can make a difference in the health of individuals is still open to question.

How does one go about assessing the general utility of a method that is embedded in enthusiasm and faith, as well as sometimes-intimidating, sometimes-impressive electronic and mechanical devices? Questions repeatedly asked by investigators such as Edward Blanchard, who has several times reviewed biofeedback's value as a clinical technique, include these:

- Which physiological functions are amenable to self-control and to what extent?
- Is the control possible only in a relatively healthy person? Or can those who have already suffered actual tissue damage also learn control through biofeedback training?
- Once a technique has been learned in the laboratory or clinic, can it be generalized to other settings, particularly to everyday life?
- Is biofeedback training always positive or at least benign? Are there persons who may be harmed in some situations?
- Who should undergo biofeedback training? Who is most likely to benefit?
- What clinical conditions are best treated by this method? Is it the treatment of choice for any conditions?

Studies on Biofeedback

Only recently have studies that carefully address these issues begun to appear in the clinical and experimental literature. Most research has been concerned with demonstrating therapeutic effectiveness. Whether conducted in clinic or lab-

oratory, these studies attempt to answer the questions a patient or therapist might ask: Does biofeedback work? Is it better than other treatment techniques the patient has tried?

Additional questions, which a public health officer or an insurance company executive might ask, have been taken up in studies comparing biofeedback with methods such as relaxation training, Zen, yoga, and Transcendental Meditation. Most have shown that the relaxation-induction procedures that almost always accompany clinical uses of biofeedback may constitute *the* active therapeutic ingredient in all of these techniques. As the title of one recent article so succinctly put it, "Are the machines really necessary?" (Silver and Blanchard 1978). Are they necessary for only some patients? Can they speed up learning how to slow down?

Research on how biofeedback works has guided the attention of many scientists toward more fundamental issues. Although primarily directed at understanding the basic processes by which biology influences behavior—and behavior biology—this research has also contributed to the evaluation of biofeedback as a treatment technique. Research by Gary Schwartz (e.g., 1973 and 1975) has shown, for example, that biology imposes constraints on the extent to which heart rate can be raised or lowered without affecting blood pressure concurrently.

The interests of patient, therapist, public health official, and scientist do, of course, overlap. No responsible physician, for example, would ignore the basic laboratory experiments on stress-related disorders if the results of this work could help his or her patients. Nor would a scientist ignore clinical evidence that might suggest new leads to understanding psychobiological processes. *Main* concerns, however, depend on where one is standing.

Studies on biofeedback are discussed in the remainder of this report along the lines of these main concerns: the scientist's concern for understanding basic mechanisms of self-control, the public health official's concern for finding the most efficient and effective treatment for the greatest number of patients, and the individual patient's and therapist's concern for whether it will work for them. The search by scien-

tists for the basic physiological and psychological mechanisms of biofeedback is described in the next section. A discussion of the scientific approach to assessing the clinical value of biofeedback follows. The fourth section briefly reviews existing evidence for the use of biofeedback for specific disorders.

2

SEARCHING FOR UNDERLYING MECHANISMS

Biofeedback may ultimately prove itself of greatest value not in the clinic but in the laboratory. After nearly two decades of research on self-regulation, there is now little doubt that people can learn some degree of control over physiological responses that were long considered involuntary. Heartbeat can be speeded or slowed; muscle tension can be altered. Something happens. The question is how.

It is not unusual for a medical treatment to be used long before either clinicians or scientists understand how it works. Even aspirin remains something of a mystery, despite its long, widespread, and frequent use. Establishing the mechanism of action is, however, probably the surest way of determining whether a treatment technique is active and specific or is simply the newest gimmick to elicit the placebo response.

What is known about the mechanism of action in biofeedback techniques has been gathered in basic psychological and physiological research. The animal experiments that provided the most powerful initial evidence for biofeedback were directed at testing some cherished beliefs about how learning

occurs. That work, together with biofeedback demonstrations involving humans, raised other questions and aroused new interest in the interaction of thought, behavior, and the body's internal milieu. In the opinion of David Shapiro and Richard Surwit, long-time investigators in the field, the behavioral regulation of physiological responses is an approach that "represents the most significant advance since Pavlov in systematic theory and method for the study of learned modifications of visceral and neural activities" (Shapiro and Surwit 1976). What can be learned, using biofeedback techniques, about the normal and pathological interaction of biology, behavior, and environment? What, in turn, are the practical implications of this knowledge?

In addition to the questions it has raised involving underlying physiological and psychological mechanisms, biofeedback has had a hand in leading scientists once again down avenues long left unexplored by American psychology—the role of volition in human experience, for one example, the nature of consciousness, for another. Interest in these subjects, anathemas to strict behaviorists, ironically grew out of a field that is strewn with behaviorist methods and gadgets (whose very use seems to imply a lack of faith in subjective experience).

The experimental and theoretical work most directly relevant to clinical uses of biofeedback has been done primarily by two subdisciplines of psychology—learning theory and psychophysiology. Interaction between the two groups of psychologists has been growing in recent years, but it is still possible to separate their literatures in the interest of understanding them. Theories to account for the evidence come from both camps, with a few drawn from the evidence of both.

Biofeedback as Operant Conditioning

Years before animal studies were done, feedback procedures were used to train humans to control biological processes consciously. But it was not until some rats had been trained to raise and lower blood pressure, heart rate, and other responses that biofeedback was taken seriously as a technique with a specific effect. The human results could easily have been

the result of "subjective-placebo, cognitive, expectancy" effects (Stroebel and Glueck 1973), while the rats were presumably not affected by bedside manner.

The research with rats had been undertaken to study a tenet of traditional learning theory. According to that theory, responses controlled by the autonomic nervous system (ANS) are learned by different means than are those controlled by the central nervous system (CNS). Biofeedback was seen as a revolutionary form of treatment because it seemed to fly in the face of this traditional division of the two nervous systems, as well as scholarly and common-sense views of their modifiability.

The distinction between the two nervous systems is closely related to how we see ourselves. Our actions, our behavior—the things we do voluntarily, consciously, and sometimes rationally—are governed by the central nervous system. Visceral (ANS) processes, by contrast, are "vegetative, involuntary and reflexive" (Brener 1977a). As we learn in grade school, our hearts beat, our lungs expand and contract, and our digestive tracts churn away without our awareness or will. We come to be grateful for the autonomy of our autonomic nervous system.

Under the right conditions, autonomic processes, like the external behavior mediated by the CNS, are subject to learning. According to traditional learning theory, ANS learning occurs, often willy-nilly, through "classical conditioning," while CNS responses can be "operantly" or "instrumentally" conditioned using established strategies to alter the learning process. The difference is between Pavlov's dog salivating to the sound of a bell and B.F. Skinner's pigeons pecking at a lever or picking out a tune.

In classical conditioning, the hungry dog learns that when a bell rings food will be available also. The bell becomes a "conditioned stimulus" that elicits the same response (salivation) as does food, which is an unconditioned stimulus. The dog is passive—automatically, involuntarily, reflexively responding to the experimenter's manipulations of bells and biscuits.

In operant conditioning, the pigeon pecks away randomly until suddenly it gets some food and, after a few such suc-

cesses, zeroes in on the lever, where pecking pays off. The hungry pigeon is "contingently" reinforced; that is, it must make the desired response (pressing the lever) or else it will not receive food. It is active. The reinforcer is a reward, like praise for a job well done, which encourages it to act in the same way again.

The belief that visceral responses cannot be operantly conditioned came about partly by historical accident. Pavlov, a physiologist, was interested in autonomic learning processes. Skinner and his followers, on the other hand, all psychologists:

> . . . consciously and explicitly eschewed interest in the "black box" of the brain and in internal physiology generally. Analogously, they limited themselves primarily to using the operant model for studying learning processes. And so the legend arose and was mistakenly codified not only as theory but as fact that the processes of operant conditioning apply only to external behaviors mediated by skeletal muscle, and not to internal autonomic behaviors. [Birk 1973, pp. 363-364]

The practice of distinguishing between the two types of learning was, itself, an artifact of history. The Russian, Pavlov, was conducting his famous experiments with dogs at the end of the 19th century, the same period when psychologist Edward Thorndike was pioneering laboratory research with animals in this country. While Pavlov observed how animals learn by associating *new stimuli* with a given response, Thorndike examined how animals learn by making a connection between a particular stimulus and *new responses*. Thorndike put his animals in situations similar to those Skinner later used. By trial and error, the animals happened on a response that resulted in food or other "satisfying consequences." So, when the animal next confronted the same situation, it was likely to make the same response. It had learned. Skinner, among the first and most influential theorists to try to reconcile Thorndike's conditioning model with Pavlov's, proposed the distinction between operant and classical conditioning (Kazdin 1978).

The difference in the two kinds of learning is complex, subtle, and somewhat arbitrary. Acquiring a taste for martinis is a case in point. A craving for gin might be *classically conditioned* by the association of the liquor with the taste of peanuts, the excitement of a flirtation, or the easing of social discomfort. A fondness for drink might also be *operantly conditioned* if the opportunity to eat peanuts, the attentions of the opposite sex, or the feelings that follow taking a drink are perceived as rewards for imbibing.

The Curare Experiments

"Failing to see any clear-cut dichotomy" in the two types of learning, psychologist Neal Miller had long "assumed there is only one kind of learning" (Miller 1969). In the late 1950s, Miller began experiments to test whether operant conditioning of visceral responses was possible. If such learning could be demonstrated, it would remove "one of the strongest arguments for the hypothesis that there are fundamentally different mechanisms of learning, involving different parts of the nervous system" (Miller 1969).

The challenge to entrenched belief was so unpopular that at first Miller had trouble getting his students to work on the problem. Nonetheless, by the late 1960s, he and his associates (first at Yale and later at Rockefeller University) had published a series of papers that created something of a sensation in scientific circles. Perhaps the most influential were the reports published with Leo DiCara on how rats had been conditioned, by operant means, to control several autonomic responses (see, for example, Miller and DiCara 1967 and DiCara and Miller 1968). Not only learning theorists, attuned to arcane issues, were excited by the articles. Because of Miller's status as a prominent learning theorist, they were widely read and discussed. The reports were generally interpreted to mean that autonomic responses could be controlled to a degree undreamed of by grade schoolers, clinicians, or research scientists. Investigators involved in biofeedback embraced the findings as convincing evidence that life-threatening or painful chronic conditions could be controlled with biofeedback.

Somatic Mediation

Miller's research addressed the issue, still not settled among scientists interested in biofeedback, of whether the demonstrated control is direct or, alternatively, is mediated by other somatic processes such as those that accompany exertion. What is actually learned when an organism is trained, for example, to increase its heart rate? Is it a change in skeletal-muscular movement (long considered subject to operant conditioning)? Does this change, in turn, produce alterations in heart rate? Miller (1978) gives several examples of how muscles elicit reflexive visceral responses: For instance, muscular activity in a limb increases blood flow to it. Researchers have also learned that human subjects rewarded for slowing or speeding heart rate usually do so by changing breathing and/or muscular tension; the more they are prevented from using these maneuvers, the smaller the learned changes in heart rate become. As a third example, Miller notes that a person can force urination to start by using abdominal muscles to increase pressure on the bladder.

> While all of the foregoing skeletally mediated reflexes are genuine learned effects, none of them indicates learning by the autonomic nervous system; all of them are dependent on a unique anatomical relationship that allows a specific visceral response to stimulate a specific receptive field. [Miller 1978, p. 378]

Miller and DiCara attempted to eliminate the influence of skeletal-muscle activity on visceral responses by paralyzing the rats with the drug, curare. Lying limp, not even breathing on their own, the rats were stimulated electrically in "pleasure centers" of the brain or allowed to escape shock as reinforcement whenever their bodies made the right responses. Their internal physiological responses were changed with the same type of methods that Skinner used to change the behavior of his pigeons.

Before long, other psychologists began to question whether paralyzing the rats did, in fact, eliminate the influence of skel-

etal-muscle activity. Several investigators (e.g., Obrist et al. 1974) argued that merely paralyzing the rat's skeletal and striate muscles did not stop its brain from firing a signal to them. The rat, as Schwartz (1973) has said, might have been struggling and tensing its skeletal muscles "in its head," moving around in every respect except physically in space. According to Schwartz, "To the extent that heart rate and muscle activity are naturally integrated at the level of the brain, reinforcement for the former will result in consistent reinforcement of the latter as well, regardless of the actual state of the muscles." Thus, while the curare studies did rule out the influence of *overt* skeletal responses, as Miller claimed, the issue of mediation by central processes was still not resolved.

The mediation issue became something of a red flag in the experimental biofeedback literature. Some investigators turned to studying the physiology of voluntary control to clarify what was going on inside the "black box."

Among clinicians, on the other hand, the role of mediation came to be seen as a red herring. The first concern of patient and therapist is control, not the purity of the mechanism for achieving it. As Miller and Dworkin (1977) have pointed out, somatic mediators such as breathing control and relaxation, which probably help patients to learn autonomic control initially, are not needed later. Bair's subjects, too, after sufficient practice, could wiggle their ears without moving other facial muscles.

An Unexpected Twist

In the wake of the reports from Miller's laboratory, many scientists tried to replicate the results. Among them were Neal Miller, Leo DiCara, and others associated with the Rockefeller group. At first, three other laboratories confirmed Miller's findings. Then, in a still unexplained turn of events, none of these laboratories (including Miller's) was able to replicate the results. Operant conditioning of ANS responses may be possible, but only by much smaller magnitudes than was suggested by the original experiments.

The failure to replicate the curare experiments led to much stock-taking. In the last few years, Miller has acknowledged

that, for now, "it is prudent not to rely on any of the experiments on curarized animals for evidence on the instrumental learning of visceral responses" (Miller 1978).

Miller has speculated that technical aspects of the experimental procedures may have been responsible for the evermore discouraging results obtained through the curare procedures. Larry E. Roberts (1978), in a thoroughgoing analysis of the extensive curare literature, goes further and suggests that procedural errors could *account for* the results of the first experiments. It is likely, Roberts concludes, "that any contribution that derived from learning was exceedingly fragile and inadvertently confounded" by other variables that may have been primarily responsible for the original findings.

The curare experiments may be most interesting as an example of the winding, sometimes wayward, path of the scientific enterprise. Nevertheless, the original results gave biofeedback its greatest impetus among scientists. If they accomplished nothing else, the original Yale-Rockefeller reports certainly dispersed what Miller has called the "bias" against the autonomic nervous system that has long pervaded Western culture in favor of the central nervous system, where the faculty of reason resides (Lazarus 1977). By engaging the interest, critiques, and interaction of scientists, the early animal studies in operant conditioning have led to other work that is slowly clarifying the profound interdependence of physiological processes with each other and with mental life. At least temporarily, the curare research may also have influenced the results of other empirical and clinical studies. As Roberts has speculated:

> Perhaps the most remarkable aspect of the curare experience is not that learning appeared to have been obtained in the early studies, but that the enthusiasm generated by these studies carried them into the published literature and raised strong expectations of success before subsequent efforts that should have replicated a robust learning phenomenon revealed the tenuous and misleading nature of the original findings. [Roberts 1978, p. 298]

In retrospect, Roberts says, the preoccupation with mediating effects seems to have encouraged neglect of basic issues, such as the properties and determinants of visceral learning. It also may have "created a readiness to attribute success to the acquisition and performance of visceral skills that may be unwarranted and premature."

Adequacy of the Model

The experiments with autonomic operant conditioning in animals produced another byproduct. Most investigators adopted the operant conditioning model to explain how biofeedback works in humans. The late Abraham Black, who was a colleague of Roberts at McMaster University in Hamilton, Ontario, was one of the strongest advocates of this point of view. In a 1977 article, for instance, he and his coauthors argued that the operant approach has more empirically rigorous concepts and methodology, as well as richer theoretical potential, than alternative views. Although much biofeedback research is atheoretical, it is based, nevertheless, on assumptions that imply a theoretical stance. Many beliefs about the nature of biofeedback training are inconsistent with operant learning theory, according to Black and his colleagues. "The main principle underlying these beliefs is, we think, that one establishes control over a response by making a subject aware of the sensations that are produced by the occurrence of the response" (Black et al. 1977a). They call this the "awareness view."

Interpreting biofeedback as a form of operant conditioning permits borrowing from the latter many well-developed principles for controlling behavior by manipulating reinforcement and controlling the stimuli that elicit behavior. Black's group finds it "astonishing that so little of the theoretical and experimental armamentarium of operant conditioning has been mobilized in research on the development of control over AS and CNS responses." As a practical tool in therapeutic settings, the experimental analysis of behavior is well established and could be drawn upon to enhance biofeedback training.

The operant approach is not without its problems, however. The main problem, according to Black and his colleagues, is

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its failure to account for neurophysiological mechanisms involved in establishing control over a response. The same is true, they point out, for skeletal-muscle responses. "We do not know any more about the mechanisms involved in training someone to wiggle his ears, for example, than we do about those involved in establishing control over skin temperature." The lack of such a theory has been in large part responsible for the concern with mediation as well as the "loose use of terms such as 'voluntary' " (Black et al. 1977a).

Biofeedback as Skills Learning

As the inadequacies of the operant-conditioning model began to surface, several investigators examined other models in an attempt to understand biofeedback. Peter Lang, for one, suggested that training humans to control a physiological response such as heart rate "resembles only metaphorically the operant conditioning of animals. The greater intellectual capacities of the human subject and the free conditions under which he performs radically change the learning situation" (Lang 1974). Lang, a psychologist at the University of Wisconsin, was one of several researchers who argued that biofeedback is more analogous to learning a skill such as playing darts or hitting a tennis ball than to an animal being conditioned.

Jasper Brener, formerly at the University of Tennessee and now at the University of Hull, England, has elaborated on the skills-learning model to derive a general theory of voluntary control. Brener contends that to control an act after being instructed to do so, you must first be able to discriminate the consequences of your actions. Being told to "raise your arm," for example, activates neural circuits that you previously had used to raise your arm. This is because the words have become associated with the sensations that follow actually raising your arm. Brener sees this process as a form of *calibration*. Because we are very poor at calibrating internal sensations, external sensory consequences, which are easy to perceive, become substitutes for our perception of internal processes. The feedback that is provided in biofeedback train-

ing can also serve this calibrating function, according to Brener.

In the ideal case, once the external feedback is removed, a person can continue to use internal feedback to identify progress toward a goal such as speeding or slowing heart rate. But if the feedback has merely been a crutch, not calibrated with internal sensations, then once the patient leaves biofeedback training, the ability to control internal processes will disappear.

Brener, among others, touches on the problem of motivating human subjects to learn voluntary control. In operant conditioning with animals, the experimenter can simply deprive a dog or pigeon of food to create strong motivation. "Such operations," says Brener, "tend to act more directly on the biological substrate than those employed in voluntary control procedures" (Brener 1977b).

In the skills-learning model, feedback is seen as *information* rather than as *reinforcement*. Although some have argued that information can act as reinforcement in human subjects, the distinction (information vs. reinforcement) is a useful one for planning clinical strategies. Drawing from the literature on motor-skills learning, especially the work of Bilodeau (1969), Shapiro and Surwit point out that,

> While reinforcement is most effective the closer it occurs in time to the preceding response, feedback operates best the closer it occurs to the next response. That is, in the feedback information conception, the delay from feedback to the next response is more crucial than the delay from the response to feedback (reinforcer). [Shapiro and Surwit 1976, p. 105]

In operant conditioning, the *schedule* of reinforcement is crucial to how quickly learning takes place and how long-lasting it is. Motor-skills learning is affected more by the frequency and detail of feedback than by its scheduling. Shapiro and Surwit say that the importance of fine-grained feedback highlights a crucial conceptual difference between feedback and reinforcement. "Feedback contains *information* which pro-

vides response-correcting properties as well as confirmation of correct performance." It is like a cue.

A further distinction between information and reinforcement may be enormously important to further use of biofeedback. According to Shapiro and Surwit, "Feedback seems to be necessary for a subtle response to be learned, while reinforcement affects performance." They observe that most investigators focusing on feedback have been most concerned with *developing* habits, while those interested in reinforcement and motivation have been concerned with *maintaining* habits. Similarly, the basic research on reinforcement and scheduling effects has been concerned with existing behavior (usually muscular-skeletal) that requires no feedback because internal physiological feedback is sufficient. Shaping or developing such a response "is normally only a technical consideration, whereas for the feedback researchers it is the main focus of their attention" (Shapiro and Surwit 1976).

So far, then, biofeedback has been used almost entirely for developing skills. Shapiro and Surwit argue that it could be more successful as a therapeutic technique if it were carried one step further. Once the desired response can be reliably elicited, it can be considered an "operant," subject to the laws of operant conditioning. In therapy, they say, this new operant can be brought under stimulus control. Shapiro and Surwit point out that the social contingencies that have been so effective in other forms of behavior modification have not been tried with physiological changes. To illustrate, they outline how they might proceed with a man who has learned to lower his blood pressure in biofeedback training: They might teach and encourage his wife to measure his blood pressure several times a day. Or, they might encourage groups of hypertensive patients to meet regularly, as do diet clubs such as Weight Watchers, "publicly recording their pressure and exposing themselves to the social consequences." The physiological response is thus put under the control of social contingencies. Without these measures, Shapiro and Surwit argue, biofeedback training will not lead to meaningful, long-term therapeutic improvement.

Biofeedback as Biological-Behavioral Interaction

The great bulk of research that has attempted to clarify the psychological and physiological mechanisms by which biofeedback works has focused on cardiovascular functioning, particularly heart rate. Among those who have been examining the regulation of heart, blood pressure, and circulatory processes are David Shapiro from the University of California at Los Angeles; Gary Schwartz of Yale, who worked with Shapiro on some of the early human experiments at Harvard; Richard Surwit at Duke University (another member of the original Harvard group); Jasper Brener of the University of Hull; Paul Obrist at the University of North Carolina; and Joseph V. Brady of The Johns Hopkins University.

In contrast to the studies on learning processes per se, biobehavioral studies have increasingly moved in the direction of trying to understand what is going on inside the black box of brain and body. When a person's behavior affects some "involuntary" function, what is it that produces the response? What is connected to what? The explicit goal in this research is to uncover the ways in which body, mind, behavior, and environment interact. Such understanding is important—not just for its own sake, but because it can elucidate disease processes, and this knowledge, in turn, can lead to treatments.

The research of these scientists is long-ranged and carefully done, their theoretical writing, rich, subtle, and difficult. Strategies and frames of reference vary. Emphasis differs, for example, according to whether they choose to examine behavior or to focus on physiology. This difference is apparent in the presidential addresses delivered in 1975 by Paul Obrist and in 1976 by David Shapiro to the Society for Psychophysiological Research. Obrist (1976), whose research has become increasingly biological, argued that, until the underlying biological mechanisms of diseases such as hypertension are understood, behavioral techniques, including biofeedback, cannot be maximally effective. Shapiro, a year later, agreed that greater biological sophistication is necessary. But he chose to "stress the value of a behavioral strategy, of defining physio-

logical changes . . . as behaviors and of examining their behavioral properties in environmental contexts in as many systematic ways as possible" (Shapiro 1977).

Much of the early basic research on self-regulation, like Miller's curare experiments, was directed at clarifying mediating processes—whether cardiovascular and other autonomic responses could be conditioned independently of somatomotor processes. Some critics dismissed the early biofeedback studies with humans on the grounds that they were confounded by ordinary voluntary learning. Some took the position that such mediation was impossible to control. Katkin and Murray (1968), for example, argued that, in human research, subjects would not only have to be paralyzed, as the rats were, to eliminate *somatic* mediation, but they would also have to be rendered unconscious to rule out *cognitive* mediation. Thought, consciousness, volition, and motivation make humans vastly more complex to study than rats.

Brener, like Obrist, attributes what he considers to be his discipline's misguided concern for somatic mediation to its lack of a biological frame of reference. From a biological perspective, he points out, variations in cardiovascular activity are but one component of an integrated behavioral adjustment. The body's systems usually work in concert. However, there are exceptions, such as when a runner's heart starts beating faster before he ever takes a step; the heart, in such instances, is preparing for exercise. In other cases, exceptions to the general rule of integrated biological-behavioral functioning may result in pathological conditions.

Obrist, with his biological strategy, has tried to clarify disease processes. One of his primary interests is understanding "how the stresses of life contribute to the etiology of cardiovascular disease" (Obrist 1976). He, too, has maintained that the somatomotor system is centrally linked to the cardiovascular system as part of the body's adaptive homeostatic functioning. Obrist has speculated that the uncoupling of this link is involved in the development of pathology. Mobilization responses associated with active coping are, in Obrist's opinion, implicated in the development of cardiac disease. As he has pointed out, this formulation appears to be inconsistent with

evidence that rats develop stomach lesions when not allowed to cope actively with aversive stress. Obrist believes there is no inconsistency—that the manner in which one copes may influence the cardiovascular system differently than the gastrointestinal system.

Another investigator interested in the disease process is Joseph V. Brady. For many years, he and his colleagues have been attempting to develop a model of hypertension in primates (e.g., Brady 1979 and Harris and Brady 1977). Using conditioning procedures, in which baboons must increase their blood pressure to avoid shock and obtain food, Brady's group has produced large-magnitude increases in blood pressure. Recently these investigators have found that increases were sustained even during long "vacations" when the baboons were not required to raise blood pressure to escape shock and receive food. Brady's work provides experimental evidence that sustained increases in blood pressure in response to stress are maintained even when the stressful conditions have been eased.

Gary Schwartz has proposed a model to account for both the occurrence of disease and the mechanism by which biofeedback might operate. Drawing on general-systems theory, especially cybernetics, Schwartz describes how the disruption of a negative "feedback loop" can lead to disregulation, which produces disorder and, sometimes, disease. Taking a drug can cause such a disruption. In fact, advertisements at times inadvertently promote disregulation, according to Schwartz (1979). "For example, famous antacid commercials in the early 1970s showed a person overeating in a pie-eating contest or shopping under stress and developing a stomachache." Instead of interpreting the stomachache as nature's own feedback of the consequences of unhealthy behavior, the commercial implied, in Schwartz's words, "Eat, eat (or shop, shop), and if you get a stomachache, don't change your environment or behavior—take a drug instead."

A stomachache in such an instance is negative feedback which can stabilize behavior by correcting "input" to the system. This notion of the effects of feedback, the central idea of cybernetics, makes it possible to examine scientifi-

cally the apparently teleological question, "How can a biological or mechanical system demonstrate intentionality, purpose, or will?" (Schwartz 1979). By its very construction, a system with a negative feedback loop *automatically* behaves in a self-regulatory ("purposeful") way.

Thus, the function of biofeedback becomes apparent: "The person does not have to 'try' to change the feedback to obtain these self-regulatory effects. In fact, the person need *not even be aware* of the complex self-regulatory processes that take place." The individual receiving biofeedback "connects" the loop by paying attention to the feedback.

Schwartz argues that if the several disciplines now trying to understand interactions between environment, behavior, mind, and brain would adopt a common general-systems framework they may begin to understand one another. He demonstrates that alternative theories about the mechanisms involved in biofeedback—operant conditioning and skills learning, for example—can be sorted out and understood within general-systems theory.

3

ASSESSING BIOFEEDBACK AS A TREATMENT

The Natural History of a New Treatment

New psychological and psychiatric treatment techniques often go through stages of apparent success and failure that can bewilder both patients and workaday clinicians. Typically, the fate of a technique can be tracked through four successive but overlapping stages:

The "Eureka" Stage: Discovery of the technique is accompanied by claims of dramatic success. The treatment catches on, and adventurous clinicians incorporate it into their practices. More successes are reported in the clinical literature.

The "Show-Me" Stage: Researchers set out to assess the value of the treatment. They attempt to determine whether it has a specific effect when applied to large numbers of patients. Is the technique itself responsible for the patient's improvement? Or, should one credit, instead, the novelty of the technique, the charisma of the originators, the faith of the patients, or still other factors that cause reported improvements? As systematic evaluations become more and more stringent, they

are increasingly likely to yield negative results. Under scrutiny, it often turns out that the treatment is not as powerful or as widely applicable as originally claimed. Naysayers have their day, sometimes failing to consider whether the procedures for evaluating treatment are, themselves, inadequate, inappropriate, or at least imperfect.

The "Rebuttal" Stage: Proponents of a treatment technique—often practitioners—take issue with the conclusions of "show-me" investigators. They might argue, for example, that the treatment, as tested, was not used appropriately or was distorted by the constraints of research design. Many well-designed and -executed assessment studies allow the therapist little leeway to exercise clinical judgment based on experience. Yet, in everyday practice, clinicians take into account a patient's response or changing life circumstances and then may revise techniques, shift to an entirely different treatment approach, or even redefine the nature of the patient's complaint.

The "Fine-Tuning" Stage: More studies are done to try to isolate the active components of a treatment and specify when it should be used. Which aspect of the technique produces therapeutic change? Which conditions and which patients respond to the treatment? Are there undesirable side effects? Do beneficial effects endure? Does the treatment work only in certain settings and in the hands of only some types of therapists?

Biofeedback went through its eureka-shouting stage in the late sixties and early seventies. The "show-me" criticisms began most noticeably in 1973 with the publication of an issue of *Seminars in Psychiatry* that evaluated the state of the biofeedback art (Birk 1973a). Since then, many of the original workers in the field have been disappointed by the results of increasingly systematic assessments of biofeedback as a treatment. By the mid-1970s, according to Miller and Dworkin (1977), the evidence was "strong enough to justify, but weak enough to require, the performance of more rigorously controlled studies." Those studies are now going on, and many have been reported in the literature. Clinicians have only recently begun to criticize such studies—in private conversa-

tions, conferences, and convention debates—but not yet extensively in print. While this regrouping is in process, many investigators have gone on to the fine-tuning stage, conducting ever more careful assessment studies that attempt to define the limits of effectiveness for biofeedback and refine the technique itself. As of mid-1980, only a few of these sophisticated studies have been published.

The Assessment Dilemma

The assessment of treatment involves methodological, procedural, ethical, and philosophical issues usually only appreciated after deep immersion in the subject. Asking whether people change leads ineluctably to asking why they change, how they change, and under what situational circumstances they change. Given the variability among individuals and the complexity of the personality and circumstance of each, knowing how to look for answers is itself a problem.

Medical-scientific procedures for evaluating treatment vary widely in formality, rigor, cost, and credibility. One clinician might try out an idea with one patient. Or a Federal agency might oversee a large-scale, tightly controlled, collaborative study at several treatment centers. However unsophisticated the evaluation procedure, reports on the outcome of treatment can provide some useful information to clinicians. But whether the treatment was responsible for reported changes can only be determined in studies that measure or control for extraneous factors not specific to the treatment itself. However, a problem arises in transferring the results of many well-controlled studies to clinical practice: How does one rule out nonspecific treatment effects and still produce useful results? This is only one of many controversies engendered by attempts to demonstrate the efficacy of treatments scientifically.

Experimental Design

As a rule, clinical investigators place greatest confidence in studies that compare large groups of subjects. In these studies, a group of subjects receiving the treatment in question is

compared to one or more other groups receiving, typically, either no treatment, a placebo and attention from clinical staff, or other types of treatment. Investigators try to account for observed differences in outcome for the two groups by subjecting the group means to statistical analysis. The group-comparison model, an extension of laboratory experimental design to applied settings, has been used most widely in the study of the safety and efficacy of new drugs.

Group experimental designs have been adopted for evaluating the effectiveness of behavioral therapies (including biofeedback), in large part through the influence of Gordon Paul, a psychologist now at the University of Houston. In several articles published in the 1960s, Paul argued the need for and demonstrated the use of large-group experimental designs. He pointed out that scientific research of any kind requires systematic manipulation of one phenomenon (the "independent" variable) to determine its effect on another (the "dependent" variable). A common mistake in much treatment research up to that time was the manipulation of a *class* of variables as if it were homogeneous. For example, to ask, "Does behavior therapy work for neurotics?" ignores, among other things, the variations in both therapies and neuroses.

Paul argued that to formulate proper research questions, the components of several "domains" of variables must be specified. Drawing on the work of other investigators as well as his own, Paul (1969) identified the variables that must be considered within three separate domains:

- *Clients or patients* vary in three crucial respects: (1) the nature of the distressing behavior that brings them to treatment; (2) personal and social characteristics (e.g., sex, age, intelligence, socioeconomic background) that remain relatively stable over time; and (3) physical and social characteristics of the patients' everyday environment (e.g., work, family, friends, use of drugs)—"essentially all the intercurrent life experiences impinging upon the client outside the treatment situation."
- *Therapist variables* fall logically into three classes:

(1) techniques used in an attempt to change the distressing behavior—the independent variable that is almost always of "most pertinent interest"; (2) the therapist's own relatively stable personal and social characteristics (including, in addition to those on which clients may vary, experience, prestige, confidence, etc.); and (3) physical and social characteristics of the treatment setting (hospital, clinic, office, whether public or private, fee structure, etc.).

- *Time*—certain events during treatment are of particular interest: initial contact, pretreatment, the initial structuring of treatment, its main application, the termination phase, post-treatment, and follow-up; time may vary within and between each of these periods; assessment may be done during each.

Once these variables have been spelled out, according to Paul, the ultimate question to be answered becomes clear. One should not ask, "Does it work?" Rather, "*What* treatment, by *whom*, is most effective for *this* individual with *that* specific problem, and under *which* set of circumstances?" (Paul 1967). Variables in all three domains outlined above must be described, measured, or controlled to begin to answer such a question. Paul, like others, also called for specifying clearly what constitutes a successful completion of treatment. At a minimum, one needs to know whether the distressing behavior that brought the client to treatment has changed in the desired direction—in and outside of treatment—without producing new problems.

Paul advocated the use of "factorial" designs, in which several independent variables (e.g., treatment technique and duration) are systematically manipulated together to determine the effect on the independent variable (the patient's distress). Such designs are best able to account for change and yield the highest "level of product," according to Paul. Series of factorial studies would yield new knowledge most efficiently.

Paul acknowledged, however, that alternative research strategies are useful in assessing treatment. Others contend that

alternative strategies, particularly the systematic study of a single case, are superior. Their arguments focus on two major problems of group studies: demonstrating a treatment effect and generalizing from the findings.

Because statistical analysis of groups is concerned only with the hypothetical "average" subject, individual differences in response to treatment are washed out. As a result, treatment efficacy can be overestimated. More usually, however, it is underestimated; even in studies of powerful drugs it is sometimes difficult to demonstrate more than a weak effect. As Hersen and Barlow explain:

> This unfortunate circumstance occurs when a treatment is quite effective with a few members of the experimental group while the remaining members do not improve or deteriorate somewhat. Statistically, then, the experimental group does not differ from the control group whose members are relatively unchanged. When broad divergence such as this occurs among clients in response to an intervention, statistical treatment will average out the clinical effects along with changes due to unwanted sources of variability. [Hersen and Barlow 1976, pp. 37-38]

The related problem in trying to generalize from a group average to a particular individual who comes for treatment is, perhaps, the clinician's biggest complaint about group outcome studies. Clinical investigators, too, find themselves on the horns of a dilemma. As Hersen and Barlow point out, a random sample of an entire population is required before statistical inferences can be made from the sample to the population. However, a study of a truly random sample provides little understanding of a particular type of individual:

> The major issue here is that the better the sample, the more heterogeneous the group. The average response of this group, then, will be less likely to represent a given individual in the group. [Hersen and Barlow 1976, p. 55]

Clinical investigators have dealt with this problem by using groups in which subjects share the same characteristics. Then, with simple logic rather than statistics, one can generalize to other individuals with similar characteristics. Yates (1976) criticizes this tactic because, he says, for all practical purposes, it is impossible to produce data extensive enough to match every client. He draws a parody to make his point:

> The clinician decides that client X, because he is 24 years old, male, divorced, with two daughters and one son, is a mechanical engineer, of the Protestant religion, and has only one leg, as well as suffering from a specific fear of heights, should be treated by systematic desensitization [a behavioral technique], involving a hierarchy of 22 items to be worked through at the rate of 2 items every 5 min, the therapy to be administered by a 20-year-old female therapist, who is single, extroverted, has three cats, and is living away from home. [Yates 1976, p. 288]

The alternative design advocated by Yates (1976), as well as by Hersen and Barlow, makes use of a single subject whose complaint is analyzed experimentally, and whose performance at several points before, during, and after treatment is compared to test the power of a technique: The subject acts as his own control. Such studies are infinitely cheaper and simpler to conduct than group studies. In fact, any clinician should be able to contribute data; Barlow (1980) has forecast that, in the near future, "series of specific problems treated by specific, well-described techniques, using simple, practical, but widely agreed on measures of change," will be collected by practitioners. Barlow argues that such a development will foster the clinical application of the results of research. In their 1976 book, Hersen and Barlow spell out what they consider to be the power and limits of series of systematic single-case studies. They and other thoughtful investigators recognize, however, that no one type of study answers all questions about the effectiveness of treatment.

Is Newer Better?

Miller and Dworkin (1977) have catalogued the reasons why many treatment techniques, including biofeedback, initially appear to be much more effective than can later be demonstrated. One reason has to do with publishing practices: Scientific and clinical journals are much more likely to publish studies with positive outcomes. Of these studies, Miller and Dworkin note, some proportion will have produced positive results by chance alone. Blanchard (1979) points out the related tendency of journals to neglect reports of research *replicating* (or failing to replicate) initial experience with a therapeutic technique. But unless observers know that a study has been replicated by independent investigators in other locations, there is no way to know that treatment effects are not due to idiosyncratic conditions, such as the relationship between one investigator and one population.

Perhaps the most powerful factor contributing to spuriously positive results in studies with new treatments is the placebo effect—the improvements in clinical conditions that result from the patient's and therapist's relationship, their belief that a treatment will work, and other factors involving the treatment setting. "Often new treatments are administered with new enthusiasm and hence produce larger placebo effects," Miller and Dworkin point out. "All too often, both the enthusiasm and the effects decline." Placebo effects are typically short lived.

Yet another factor that leads therapists to believe that a treatment is effective is the body's natural, "wonderful capacity to recover from a great variety of infections, physical injuries, and psychological trauma." Improvement during treatment—new or old—may be no more than the result of spontaneous recovery.

The stage of development of a treatment is one factor that determines appropriateness of research design. For logical, practical, and ethical reasons, a few cases are treated before a technique's effectiveness is tested with large groups. As long as it is not claimed that such studies show the utility of a technique for a broad population, they can contribute to knowledge about treatment.

Sometimes, sophisticated evaluation procedures simply are not necessary. For example, as one investigator has noted, no controlled statistical trials are needed to demonstrate the value of surgically rejoining a severed part of an arm or leg. "The efficacy of the procedure has been made apparent by historical comparison" (Feinstein 1980).

The fact remains, however, that, for now—despite their limitations—large-group comparative studies are accepted as the best form of evidence for judging the efficacy of treatment procedures.

Related Considerations

Uncontrollable circumstance and procedural problems can jeopardize even the simplest study. When a therapist falls ill, for example, a patient might interpret the absence as rejection and drop out of the study. Investigators who undertake large-scale studies can confront sometimes insurmountable problems in carrying out their plans: They may have difficulty locating enough subjects with identical or sufficiently similar complaints. Financing the investigation may be problematical. Critical research personnel may quit, subjects move across the country, machines break down, funds dissipate, cooperation cease. But even the best experimental designs—carried out faithfully, meticulously, and with good luck—cannot answer every question about the value of a treatment.

Experimental rigor may be sacrificed sometimes for ethical reasons—when, for example, the well-being of a subject would be compromised by rigid adherence to a research plan. Ethics enters into the selection of an experimental design as well. Many clinicians find it difficult to justify a no-

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treatment control group when patients are suffering. Similarly, placebo-control conditions are questionable when the treatment being considered is believed to produce powerful effects.

Criteria for Assessing Biofeedback

Methods for determining reliably the clinical value of a treatment procedure are still being developed. For this and other reasons, the standards of acceptable evidence in the clinical literature appear to differ from one treatment modality to another. Studies on biofeedback as a treatment have very recently become more rigorous in response to criticisms made by several reviewers—notably Edward Blanchard, at the State University of New York at Albany, Neal Miller at Rockefeller University, and William J. Ray and his colleagues at the Pennsylvania State University.

The earliest thorough reviews were done by Blanchard and various colleagues. Blanchard's reviews, some done with Larry D. Young (1974), Leonard Epstein (1977), and others (e.g., Silver and Blanchard 1978 and Williamson and Blanchard 1978a), are repeatedly cited by other reviewers. To a large degree, Blanchard's evaluations reflect the most stringent standards used to rate the clinical evidence on biofeedback.

In a 1979 review, Blanchard spells out the criteria that he now believes appropriate for evaluating biofeedback in the clinic. In his view, the most important criterion is the extent to which the treatment produces *clinically* meaningful changes. In 1973, Blanchard and Young had argued that an effect is clinically significant if it achieves a certain magnitude—lowering blood pressure by a specified amount, for example. Following that review, Bernard Engel (1974), whose studies with cardiac patients were among the earliest clinical applications of biofeedback, criticized Blanchard and Young's criterion. Engel argued, and Blanchard now agrees, that a change can be considered significant to patient health only if it is obtained in patients with a clinical disorder. Blanchard points out that a study which produces statistically significant, but clinically trivial, changes cannot be considered good

evidence even if it has met the strictest assessment standards.

The rigor of experimental design is the second criterion by which Blanchard evaluates studies of the clinical utility of biofeedback. He identifies five types of design, each increasingly more rigorous, each allowing more confidence in a study's conclusions:

- *Anecdotal case reports.* The clinician makes no attempt to control for specific aspects of the treatment or other events taking place in the patient's life during treatment.
- *Systematic case studies.* Data on the patient's functioning are recorded before treatment begins to establish a baseline for similar measures taken as treatment progresses. Again, the influence of events outside of the treatment setting is not ruled out.
- *Single-group outcome studies.* At least several patients are treated with the technique; the experimenter notes what percentage of them change, but does not try to determine nonspecific effects of the treatment or events outside of treatment that influence the change.
- *Single-subject experiments:* These are similar to systematic case studies because measurements taken before and during treatment are compared. However, the potential influence of outside events is taken into account. With this design, the treatment is stopped, and the patient's functioning is again measured. If symptoms revert to baseline, then the treatment, rather than other events in the patient's life, is presumed to have been responsible for earlier changes. If symptoms do not return, however, it does *not* prove that the treatment was ineffective. (For example, if an infection does not return after penicillin treatment, it certainly does not mean that the drug did not work.) Another precaution: Single-subject experiments must be replicated systematically to rule out the possibility that changes were idiosyncratic to the one patient under study.

(For a discussion of single-subject designs in biofeedback research, see Barlow et al. 1977.)

- *Controlled group-outcome study.* With this design, one group of patients receives the treatment in question and one or more others receive no treatment, a placebo, or another type of treatment. When the control group receives a placebo and comparable attention from treatment staff, one can rule out the possibility that nonspecific factors were responsible for changes in the experimental group. Any control group, however, allows one to discount the possibility that changes were due to patient experiences unrelated to treatment.

Comparing the new treatment with the best available alternative is one commonly recommended control procedure. Different versions of the new treatment also may be compared to isolate the effective components (Miller and Dworkin 1977).

As discussed above, group studies have the disadvantage of masking individual differences in response to treatment. Blanchard therefore recommends determining the percentage of patients who have responded with clinically significant changes.

Adequate followup is also important. Blanchard points out that to evaluate a treatment, one must obtain a result by the end of treatment, and one must also know what happens after treatment has stopped. The longer the treatment effect lasts, the more likely it is that a real change has taken place. Miller has repeatedly pointed out (e.g., Miller and Dworkin 1977) that chronic conditions naturally fluctuate in severity. Patients come to treatment when they are suffering. In the normal ebb and flow of a condition such as migraine headache, the next fluctuation is likely to be an improvement. Thus, patients may terminate treatment, believing themselves cured. The longer improvement persists thereafter, the more likely it is that the change resulted from the treatment.

The ultimate benefit of biofeedback in a patient's life is another issue that concerns Blanchard and his colleagues, Miller and Dworkin, and most other investigators. Can the

control demonstrated in clinic or laboratory be transferred to everyday situations? Many clinical reports have failed to note whether patients are able to use their new-found skills when faced with stressful life events. Other treatment teams incorporate home practice as part of their routine use of biofeedback (e.g., Budzynski et al. 1973). Miller and Dworkin (1977) warn that failure to find out if the treatment effects have generalized beyond the initial training situation creates difficulties in interpreting the adequacy of therapeutic experiments and may also hold real hazards for the patient. A hypertensive patient who has learned to control blood pressure on demand in the laboratory, for example, might be taken off medication. Unless the treatment effects have been generalized, under stressful conditions, the blood pressure may once again become dangerously elevated.

Other harmful effects might be produced by biofeedback. Miller and Dworkin say that the early glowing reports about the alpha state must be weighed against other evidence that some subjects feel out of control when experiencing alpha brainwaves (Sterman 1973). Other potential side effects include: terrifying thoughts (possibly accompanying EMG or hand-warming relaxation procedures); hypnotic imagery (such as that which precedes sleep, which may be produced by brainwaves in the theta frequency); symptom substitution; and visceral neurosis (a preoccupation with visceral phenomena) (Miller and Dworkin 1977).

Blanchard considers one final factor important in evaluating biofeedback—the ability of patients to alter the response for which feedback is given, which is not always the response of clinical interest. Patients may, for example, experience a reduction in tension headaches without actually being able to reduce muscle tension. If they are unable to demonstrate control, any improvement in symptoms probably is due to placebo effects.

In addition to the above criteria, reviews of clinical biofeedback rate the value of specific applications of the technique by broad criteria recently made explicit by Kazdin and Wilson (1978). These investigators extend usual outcome measures to include, for example, breadth and durability of thera-

peutic change, and they recommend that treatments be evaluated along other lines: relative efficiency (e.g., group vs. individual); costs in terms of professional expertise; and cost and acceptability to patients.

Placebo—Rule It Out or Use It?

The role of placebo effects has been of particular interest to biofeedback investigators, perhaps because it has been difficult to sort out the active components from placebo effects in successful clinical applications of biofeedback. According to Arthur K. Shapiro, a leading authority on placebo effects, the history of medicine before the discovery of germs was largely the history of the placebo response (Shapiro 1971). Even drug treatments, which presumably produce direct chemical changes in biological systems, are enhanced by the placebo effect. Frank and his associates (1978), for example, gave what was described as a "new pill" to psychiatric patients, who responded by feeling better and displaying fewer symptoms. The pill was a placebo.

Commenting on medicine's historical reliance on placebo effects, Miller observes:

> During thousands of years of prescribing what are now known to be useless and often dangerous therapies—bloodletting and puking and medicines such as the eye of newt, crocodile dung, fly specks, flesh of vipers, the ground-up sole of a worn-out shoe, and the spermatic fluid of frogs—physicians nevertheless maintained their position of honor and respect. Shapiro (1960) argues that this was possible primarily by virtue of the powerful placebo effect and the ability of the human body to produce its own recovery. [Miller 1975, p. 356]

As Miller and Dworkin (1977) note, "Placebo effects are particularly prominent with some of the symptoms that have been involved in biofeedback treatment." Headaches, in particular, respond "flagrantly" to placebo medication, and high

blood pressure has been shown to be influenced by sugar pills.

Controlling for Placebo Effects

The now-standard procedure for evaluating new drugs is the double-blind experiment, in which neither patient nor therapist knows which drug is being administered. The first condition controls for the patient's enthusiasm and faith, the latter for the therapist's. Miller and Dworkin recommend that the same model, or a similar one which would achieve the same goal, be used for biofeedback experiments.

Devising a control group to rule out placebo effects is a special problem in biofeedback research. Katkin and Goldband (1979) have discussed this problem at some length. Somehow, they note, control patients must be subjected to procedures that are indistinguishable from those used for patients receiving active treatment. Often, experimenters will attach the same kinds of electrodes and thermistors to both groups of patients, but will give false feedback—perhaps a recording of another patient's responses—to the control group.

But if the subjects can actually detect their own responses, false feedback will backfire and will not work. The problem is particularly troublesome when muscular activity is being monitored. For example, a man who was being treated for stuttering was given feedback from his larynx muscles to aid in reducing their tension (Hanna et al. 1975). When feedback from another person was substituted, he complained that the machine had gone awry. His own internal feedback contradicted the external feedback. Attempting to deal with this problem, experimentalists have outdone one another with cleverness (e.g., Cohen et al. 1977), but the fundamental problem remains.

Another problem arises with responses that cannot be discriminated. Katkin and Goldband explain that, according to Brener's theory (1977b), responses must be discriminable before they can be altered by contingent reinforcement. Yet, if they are discriminated, the subject is likely to know that the feedback is inaccurate. "Thus, despite its inherent appeal, the use of false physiological feedback as a placebo control for

biofeedback is probably inappropriate and ineffective," Katkin and Goldband conclude.

They recommend that, to discount placebo effects, ideally a researcher should start with a theoretical model that identifies therapeutic mechanisms precisely. The next step is to choose a form of placebo treatment which resembles the active treatment in all or most respects, but which cannot be expected to operate according to its principles. For example, feedback given to control patients can be delayed or otherwise modified in ways that render it ineffective (at least according to the tenets of learning theory). It is not legitimate, argue Katkin and Goldband, "to define placebo effects as those which are not understood; rather, *a placebo effect is one which leads to positive outcome when knowledge of its mechanism suggests that it should not*" (italics added).

Katkin and Goldband, like many investigators, see biofeedback as a specific form of psychotherapy, even though they believe that its effective principle is operant reinforcement. Assessing the effectiveness of biofeedback independent of other features of the therapeutic situation is, therefore, subject to some of the same problems that bedevil psychotherapy research. Just entering treatment, where it is clear that one is expected to get better, can produce powerful placebo effects. The relationship with the therapist may exert even more influence on the outcome of treatment. A situation that controls for placebo effects "should look like therapy, should sound like therapy, and *should cause the patient to expect that he is receiving therapy*," according to Katkin and Goldband. But not enough is known about the interpersonal interactions that go on in therapeutic settings to allow an adequate placebo to be designed. "How does one create a continuing interpersonal relationship that is presented to the client as therapy and which can be demonstrated to be incapable of actually being therapy?" To the extent that such so-called placebo characteristics as the patient's expectations of success and the therapist's warmth or empathy are the effective agents for change, they *become* the active treatment and are no longer placebos.

Positive Aspects of Placebo

The problem of excluding the influence of the placebo response presents a dilemma similar to that facing researchers trying to rule out the mediating effects of somatic learning in their attempts to achieve operant conditioning of visceral responses: Since the placebo or mediating effects serve a useful purpose, why insist on purity of either therapeutic or learning mechanism? As Miller and Dworkin say:

> The very power of the nonspecific placebo effect that makes it such a nuisance in trying to determine the value of a specific type of treatment means that it is medically important. We do not yet understand enough about the variables affecting it and how these variables act to produce therapeutic changes. Thus, it is important to stop regarding it as a mere nuisance and to design studies to understand it in its own right. [Miller and Dworkin 1977, p. 145]

Stroebel and Glueck (1973) speculate that biofeedback may make its greatest contribution as the "ultimate placebo" by "squarely placing both the placebo effect and the patient himself in a position of importance in the prevention and treatment of illness." Because most people have come to expect to be passive recipients of health care, they may, according to Stroebel and Glueck, "require personal demonstrations through a structured period of self-learning to incorporate the concept of individual responsibility." They suggest that biofeedback may be an ideal procedure for such structured self-learning.

4

EVALUATING SPECIFIC APPLICATIONS OF BIOFEEDBACK

Like any form of treatment, biofeedback is more effective in treating some disorders than others. One might have concluded, from reading the early literature on the subject, that such was not the case. Because biofeedback promised control over functions that were previously thought to be autonomous, the procedure was readily bestowed with almost magical potency and was sometimes even lauded as a panacea. It seemed to allow Westerners to shift into another level of consciousness—one which seemed to mimic, or perhaps even duplicate, that of Eastern mystics. If a yogi can lie on a bed of nails why can't a Western man or woman put this power to a more pragmatic use, such as curing disease?

In the early days of biofeedback, many patients *did* get better. Many still do—just as some yogis still sleep on nails. Whether faith and enthusiasm, generalized relaxation, or some specific learning effect is responsible for the therapeutic benefits of biofeedback is still not known. Now that skeptics have begun systematic evaluations, and negative reports are becom-

ing more common, the rash claims of the early days have also subsided, and a defensive posture is evident in much clinical literature on biofeedback. In practice, the contribution of placebo factors to the successes of biofeedback treatments may diminish as clinicians become aware of the negative findings. Undoubtedly, some patients who might have improved under the care of a biofeedback enthusiast will now fail to get better simply because they will be deprived of this aspect of the placebo effect.

Years ago, when Edward Taub began experiments in controlling skin temperature with biofeedback training, he found out just how much the trainer's attitude can contribute to the success or failure of the technique (Taub 1977). One experimenter, a woman, in Taub's Silver Spring, Md., laboratory did not believe that feedback training would work but, in the interest of scientific objectivity, she tried to maintain a neutral manner in the presence of the subjects. She was able to train only 2 in 22 subjects to raise their skin temperature. A second woman experimenter believed in the method and, despite herself, enlisted the subjects as virtual collaborators in the project. She obtained results that were almost exactly the opposite of the first trainer's: 19 of 21 subjects succeeded in raising their temperatures.

Such a dramatic contrast suggests that interpersonal factors and the therapist's attitude are powerful influences in biofeedback training. This difference is especially arresting because skin temperature training for Raynaud's disease (characterized by cold hands and feet) has often been cited as a type of biofeedback that functions in a relatively specific manner—that is, the feedback training contributes to therapeutic successes above and beyond placebo and other nonspecific factors. Several investigators (e.g., Shapiro 1979) have suggested that feedback training is most likely to be clinically useful when it is specifically directed at changing an abnormal response. Warming the hands to counteract Raynaud's symptoms is such a case. (See Yates 1980 for a discussion of the specificity issue.)

Studies designed to tease out the active components of biofeedback training (which Taub's were not) are now being done

on a whole range of disorders for which the technique has shown some promise. The amount and quality of research on a disorder do not always correspond to the frequency of clinical application, however. For example, heart-rate control has been the subject of some of the best basic research. Blood-pressure control has also been studied extensively, especially as a clinical tool. Yet biofeedback is rarely used to speed or slow heart rate in actual practice. Blood-pressure feedback is used, but not widely. On the other hand, biofeedback is probably more often used to treat headaches than any other disorder; yet, the research that has been done, especially on migraine, may not support such widespread application.

What follows is a brief summary of the accumulated research findings on the efficacy of biofeedback for the disorders most commonly treated with the technique. The conclusions are drawn from recent reviews of the research literature done by experts in the field. For each disorder, a representative study or studies of special merit are cited. Because headaches are now often treated with biofeedback, and because the evidence for this practice is far from complete, the section describing this research is detailed in order to highlight some of the problems in assessing biofeedback as a treatment.

Headache

Headaches are nearly as common as the common cold. Of those that recur frequently, migraine and tension headaches are the most prevalent. It has long been believed that women are more prone to both types of headache, but recent studies challenge this belief (Adams et al. 1980). Both migraine and tension headaches are thought to be triggered or aggravated by psychological stress, and both are now often treated with psychological techniques such as biofeedback or relaxation training.

Experts distinguish between the two common types of headache both by the character of symptoms and by physiological mechanisms thought to cause pain. The technical terms for the two conditions imply these differences: Migraine or "vascular" headaches involve contraction and dilation of

the blood vessels in the head, while tension or "muscle-contraction" headaches are associated with tense muscles in the head and neck.

Typically, migraine starts as a dull ache in the forehead or temple or behind the eye. The pain rapidly becomes severe and throbs; later, it becomes continuous. In two out of three cases, the pain is confined to one side of the head. Most migraine patients also suffer nausea and vomiting during an attack. Most are unusually sensitive to light.

In contrast to the throbbing pain of migraine, the pain of tension headaches is dull, persistent, and undulating in intensity. Often, the headache is experienced as pressure or a band around the head. In mild cases, headaches develop during or after stress. Many people with chronic tension headaches appear to be suffering from some of the common symptoms of anxiety or depression. Missing teeth, an uneven bite, or stress-induced tension in the jaw and neck can produce similar pain.

> Chronic jaw-clenchers commonly complain of pain over the contracting temporal and masseter muscles. The constant frowners have bifrontal headache and the "stiff-necks" describe occipital pain. These sites may flow into one another so that the patient feels pain "all over the head." [Lance 1978, p. 107]

Some experts believe that overactive sympathetic nerves—those which activate the body to meet a real or imagined threat—may be involved in both vascular and tension headaches. Physiologically, a migraine is thought to start with the constriction of blood vessels within the skull. During that phase, when the blood supply to the brain is reduced, migraine sufferers often experience visual disturbances. Responding to its internal self-regulatory systems, the body rebounds, dilating cranial arteries, and consequently increasing cerebral blood flow. Distension and increased sensitivity in the vessels are thought to produce the pain (Lance 1978). Evidence of concurrent physiological processes involving the neurotransmitter serotonin supports the long-held belief that migraine is related to stress through increased sympathetic activity (Price

1979). "Migraine," according to one headache expert (Lance 1978) "may be considered as a hypersensitive protective mechanism for preserving the integrity of the brain against any sudden change in the internal or external environment." The pain itself, although subjectively the most troublesome aspect of the headache, may be merely a byproduct of neurovascular reactions that serve some purpose.

Tension headaches occur through a much simpler mechanism, according to common medical belief: Stress-induced chronic contractions of the face, scalp, and neck muscles produce the pain. This simple explanation may be far from accurate, however. Recent research (e.g., Epstein and Abel 1977 and Bakal and Kaganov 1977) has shown that muscular tension, as measured by the electromyograph (EMG), does not correspond to patients' reports of headache. Martin and Mathews (1978), who also found that patients had significantly lower forehead EMG activity during headaches than at other times, speculate that both migraine and tension headaches may occur through similar physiological mechanisms involving the blood vessels and that the difference between the two types of headache is largely one of degree.

Chronic headache sufferers, as the television commercials say, seek relief. Unlike a symptom such as high blood pressure, a headache interferes with work and play. Usually the remedy is a medication that either relieves the pain or prevents the attack in the first place. But medications can produce side effects and may not always work. Furthermore, they can lead to dependencies that require increasing dosages. They also fail to deal with the stresses that contribute to the problem in the first place. Biofeedback and other psychological treatments hold promise because they do not involve some of the hazards related to drug treatment. They are sometimes administered as if they were drugs, however, with little attention paid to the sources of stress.

Migraine Treatment

Biofeedback treatment of migraine, which is usually done through the unlikely method of warming the hands, was dis-

covered by accident. Sargent and his colleagues (1973) at the Menninger Clinic in Topeka, Kans., were training a woman to control brainwaves, reduce the EMG readings in her forearm, and increase the blood flow in her hands. When she reported that a migraine attack had subsided while she was warming her hands, the Menninger team was intrigued. Subsequent clinical trials involving a form of relaxation known as "autogenic training" and feedback for changing finger temperature led the group to conclude that the technique showed promise as an alternative to drug treatment for migraine. They hypothesized that the mechanism involved some lessening of sympathetic nervous-system activity—not, as is sometimes believed, the transfer of blood from head to hands. (The so-called "hydraulic" explanation of the technique has, however, received some support; see Yates 1980.)

The Menninger studies have had tremendous influence. Sargent and his colleagues have continued to study the possibilities of the technique. Their studies have been criticized, however, for their lack of appropriate controls (Blanchard et al. 1979a and Price 1979) to provide assurance that the reported improvements were not produced by placebo or other nonspecific factors. Blanchard and his colleagues, in a 1979 review of the headache studies, point out that while subsequent studies were done in several clinics, at the time of their review there were "*no* well-controlled group outcome evaluations of the combination of temperature biofeedback and autogenic training versus either no treatment or an attention-placebo treatment." Several studies have, however, compared the technique with other forms of psychological treatment (e.g., Andreychuk and Skriver 1975), including other forms of biofeedback (e.g., Lake et al. 1979). Other studies (e.g., Price and Tursky 1976) have attempted to identify the mechanism by which biofeedback might reduce headaches. And at least one migraine study (Feurstein and Adams 1977) has used a systematic, single-subject design to examine the patterning of responses during feedback training.

In a followup study, the Menninger group (Solbach and Sargent 1977) reported that 74 of the 110 patients in their sample completed the training. Of these, 55 were judged to be

moderately or more improved by the end of 9 months. Further followup on these patients and those who had dropped out before completing the training course suggested that the successful completers continued to improve; the dropouts did also, but to a lesser degree. Most patients attributed their improvement to staff interest and support and to the relaxation exercises. Relaxation practice was continued at home (along with the hand-warming exercises) by completers more often than by the dropouts.

Some investigators have attempted to evaluate the effect of biofeedback training alone. In a controlled group-outcome study involving 11 patients, Mullinix and his co-workers (1978) used a form of false feedback for a control group that received the same attention as did the active-treatment group. Although the experimental group was able to increase hand temperature better than the control group, there was no difference in headache improvement.

Attempts to reduce migraine with relaxation alone have been assessed and compared to biofeedback training plus relaxation (e.g., Andreychuk and Skriver 1975 and Blanchard et al. 1978). Improvement rates for biofeedback training range from about 50 to 85 percent of patients, while those for relaxation training range from 35 to 80 percent (Blanchard et al. 1979a).

In a 1-year followup of the 1978 study by Blanchard's group, which compared patients treated with either progressive relaxation or temperature feedback combined with autogenic training, all patients had maintained improvements demonstrated at the end of treatment (Silver et al. 1979). The gains were maintained after a year despite the failure of some individuals in both groups to continue regular practice. The similarities suggest that both treatments may be acting by a final common pathway of relaxation, according to the researchers. They speculate that patients learn to respond to stress with a calm, relaxed attitude and a reduction in the overall level of sympathetic arousal.

Several studies (e.g., Turin and Johnson 1976 and Kewman and Roberts 1976) have trained some subjects to *cool* their fingers in an attempt to learn whether the warming procedure

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was specifically related to reductions in migraine. In most of these studies, subjects who were able to cool their hands did not experience a reduction in headache symptoms, a finding that suggests to some investigators a specific link between finger warming and migraine reduction. Kewman and Roberts think otherwise. Their study, which used double-blind, group-comparison control procedures, also showed that cooling the hands did not reduce headaches. But they attribute the results to a failure to reduce sympathetic arousal. Any treatment that can lower arousal is likely to decrease the frequency and intensity of migraines, they conclude.

Another strategy used in the experimental treatment of migraine with biofeedback is the attempt to affect the blood flowing through cerebral arteries at the site. Friar and Beatty (1976), for example, compared patients trained to reduce the amplitude of the pulse either over the extracranial artery most affected during migraine headaches or in the finger. The first group showed a significant reduction in the frequency of headaches, while the only improvement shown by the finger-pulse group was a reduction in medication use. The experimental group showed a reduction of pulse amplitude in both head and hands. This treatment strategy is directed at interrupting a headache attack already under way rather than preventing its onset.

Careful reviewers conclude that generalized relaxation, which apparently acts by inhibiting sympathetic nervous system activity, is probably responsible for whatever treatment effect has been obtained in migraine headache patients undergoing biofeedback training (Price 1979, Turk et al. 1979, Blanchard et al. 1979a, and Yates 1980). Their conclusions, of course, are extremely tentative because researchers have not yet adequately tested this application of biofeedback.

Tension Headache Treatment

Biofeedback training for muscle-contraction headache was first used by Thomas Budzynski, Johann Stoyva, and their associates at the University of Colorado Medical Center in Denver. These investigators continue to dominate the field, although the treatment procedure they devised is now very wide-

ly used. The procedure includes relaxation training and feedback (from an electromyograph connected to an electrode attached to the forehead about an inch above each eye). The EMG feedback gives information on muscle tension, not only in the forehead, but in the entire head area, possibly including the upper part of the trunk (Basmajian 1976). The emphasis in the Budzynski-Stoyva approach is on relaxation, assisted by the EMG feedback. The investigators have characterized the effect produced by this training procedure as "cultivated low arousal" (Stoyva 1977).

In the first controlled group-outcome study done in biofeedback, Budzynski et al. (1973) found that patients who received feedback and relaxation training did better than control patients, who received either a form of false feedback or no treatment at all. Commenting on this study, Shapiro and Surwit (1976) point out that the control group probably was not adequate. The patients were given a form of sham feedback, which Budzynski and Stoyva tried to disguise by telling subjects that the clicking of the feedback was meant to help them relax. "It seems obvious," say Shapiro and Surwit, "that such a procedure would have no more credibility than telling the subjects that the feedback of others was their own."

Other studies on tension headache have used EMG biofeedback alone (e.g., Philips 1977) or have compared relaxation to biofeedback (e.g., Martin and Mathews 1978). Cox and his colleagues (1975), in a well-controlled study, for example, found that patients who received relaxation training, either alone or combined with biofeedback, were subject to fewer and less intense headaches than those in a placebo control group who were given a sugar pill.

Overall, the evidence supports the effectiveness of biofeedback-assisted relaxation or relaxation alone in the treatment of tension headaches. Only a few reports show some change as the result of feedback training alone. Most reviewers find little in the current evidence to recommend biofeedback over relaxation alone, however (e.g., Silver and Blanchard 1978, Blanchard 1979a, Turk et al. 1979, and Yates 1980). A task force of the Biofeedback Society of America (BSA), interpreting the evidence somewhat differently, concluded that

frontal EMG feedback *can* reduce muscle tension faster and to a greater degree than relaxation alone (Budzynski 1978).

The BSA group points out the difficulty of comparing studies that are not close replications of each other:

> Factors such as thoroughness of subject screening, criteria for inclusion in the study, bandpass of the biofeedback device [a filter that controls the range of signals], type and quality of feedback (pleasant, aversive, frustrating), length of training, instructions to subjects, warmth/cool personality dimensions of the experimenter, and, of course, experimenter bias confound results. [Budzynski 1978, p. 420]

Presumably, a different weighting of the importance of each of these factors leads to the difference in interpretation of the evidence.

Belar (1979) cautions clinicians against making premature judgments based on Silver and Blanchard's (1978) conclusion that relaxation and frontal EMG biofeedback are equally effective in treating tension headache. She notes several possible confounding factors in the studies on which Silver and Blanchard base their conclusions. For example, she points out that none of the studies required subjects to relax frontal muscles to some criterion level. Adequate treatment trials were instead defined by the number of training sessions. According to Belar, this is conceptually equivalent to measuring a drug dosage by the number of pills dispensed rather than by the level of concentration of the drug in the blood.

Belar also points out the importance of obtaining several measures of outcome. Tension headaches involve, in addition to pain, a physiological response and subjective experience. The pain itself can be measured by the degree of incapacity and medications used, as well as by other criteria. Some studies neglect objective measures of change, relying solely on the patients' own reports.

Both Budzynski (1978) and Turk and his colleagues (1979) call attention to treatment strategies that attempt to alter habits of thought which may lead to disturbing emotional

and behavioral responses. By learning to identify the kind of thinking that precedes a headache, the patient can know when to interrupt a pattern of thought that is maladaptive. Holroyd and his co-workers (1980), for example, conclude from a series of their studies that modifying EMG activity may not be critical to controlling tension headaches. It is more important for headache patients to monitor the conditions leading to headache and to engage in some type of coping response that will prevent it, according to these researchers. In some cases, the coping response may involve, instead of muscle relaxation, assertive behavior, withdrawing from stressful situations, or re-evaluating the conditions that lead to headaches.

Treatment Concerns—The Case of Headache

Headache treatment highlights other, sometimes neglected, problems in managing psychophysiological disorders.

Physical Disease

Strictly organic pathology can be responsible for the headache. Even if psychological factors are implicated in the onset of some kinds of headaches, they are not necessarily the primary cause. Miller (1978) believes that a physical examination is necessary before any behavioral therapy is used. Otherwise, conditions that could be treated by conventional medical means might be neglected, such as a brain tumor that may be operable if caught in time. Some researchers (e.g., Blanchard and Epstein 1977) argue that biofeedback training of people with psychophysical diseases is done best in a setting where there is ready access to medical evaluations of organic disease. Others (e.g., Cox 1979) will use biofeedback and relaxation techniques only with patients who have been referred by neurologists.

Psychological Disorder

The psychological component in headaches and other stress-related disorders in all likelihood serves some purpose. For example, someone who, for whatever reasons, does not

like to ask for help may find headache or other physical symptoms more acceptable as an unconscious means of gaining the attention and care of physician, family, and friends. Whether it precedes or follows the initial appearance of chronic symptoms, such a motivating factor can be powerful. According to Budzynski (1979), chronic migraines are quite often associated with such secondary gains. Some tension headache patients also derive secondary benefits from their illness (Budzynski 1978). In headache patients, Budzynski says, biofeedback training can lead to one of four outcomes:

- The patient actually learns to alter the response voluntarily, and the headache gradually abates.
- The patient learns to alter the response (such as EMG readings from the forehead), but the headaches do not improve. Budzynski speculates that, in such a case, the patient consciously or unconsciously does not want to give up the headaches.
- The patient cannot alter the response, but the headache disappears anyway. This outcome, says Budzynski, suggests a short-term placebo response. The first major stress the patient encounters will probably bring back the headaches.
- The patient may fail to learn the response and may continue to suffer from headaches. Like the second example, such a patient may be reluctant to give up the symptoms. But Budzynski suggests that the difficulty may also reflect a fear of relaxing deeply, letting go, or feeling vulnerable.

If psychological factors are important in maintaining a disorder, simply removing one symptom may cause more serious symptoms to appear. For that reason, some researchers (e.g., Budzynski) advocate that biofeedback training be done in settings where routine psychological assessment accompanies the training and some form of psychotherapy is available.

Some reviewers have noted that biofeedback procedures focus almost exclusively on physiological responses. In painful conditions such as headache, however, psychological adap-

tations play an important part. Turk and his colleagues believe that, "Teaching voluntary control of physiological functioning may not be sufficient, since patients not only must control their physiology but they must be capable of dealing effectively with their environment." Turk and associates believe that biofeedback should be used in conjunction with other physical and psychological therapies rather than alone.

Cox takes a similar view. He and his associates at the University of Virginia assess both physiological and psychosocial factors contributing to headaches. They try biofeedback, but, if it does not produce a physiological change in two sessions, Cox and his co-workers try either behavior or family therapy. Emphasis is on "teaching patients skills that they will need to refine, generalize, and implement on their own."

The BSA task force also notes that biofeedback is not the sole technique of value for tension headaches (Budzynski 1978). This group makes the important point that the actual therapy a patient receives often depends on the professional training of the practitioner. Medical clinics use drugs in addition to biofeedback but rarely psychotherapy or behavior therapy. Psychiatric clinics are likely to use both drugs and psychotherapy to augment biofeedback. Psychology clinics usually use some form of behavior modification and stress-coping techniques, but rarely drugs, in addition to biofeedback training. Thus, biofeedback, like other treatment techniques, can be as varied as the clinicians who use it.

Relaxation and Biofeedback

A third and obvious concern in biofeedback treatment for headache involves cost. If, as has consistently been shown, relaxation techniques alone are as effective as relaxation with some form of biofeedback, why not dispense with the feedback training? Most forms of relaxation training, such as Schultz and Luthe's (1959) autogenic training, Jacobson's (1929) progressive relaxation, or Benson's (1975) relaxation training, cost little or nothing but the patient's time and willingness to practice as little as 20 minutes a day.

In an analysis of the role of relaxation in biofeedback training of headache (and other) patients as well as normal sub-

jects, Linda Tarler-Benlolo (1978) concluded that research to date documents equally positive results for relaxation or biofeedback methods used alone. Because few studies are directly comparable, however, it is difficult to know which aspects of treatment are essential. Is it the number of training sessions? Their length? The way the instructions were delivered? Was home practice required? Should it have been?

Tentatively, Tarler-Benlolo concludes that:

- According to physiological measures, subjects do not always recognize when they are relaxed. After little or no special training, subjects frequently reported feeling relaxed but "did not seem to be consciously aware of the finer or deeper levels of relaxation that they reached following training as was evidenced by physiological records."
- The best form of training has not yet been determined, although a combination of relaxation and biofeedback might be optimal.
- Relaxation training that involves passive mental concentration seems to be favored by investigators who report in the research literature.

If and how relaxation and biofeedback interrelate remain to be demonstrated, according to Tarler-Benlolo. Does undergoing one treatment make it easier to benefit from the other? Does one form of relaxation work better than another? One form of biofeedback? Some combination of the two techniques? Is the treatment of choice determined by the disorder or by an individual's unique psychophysiological pattern of responding or by both?

The issues concerning the role of relaxation in biofeedback are far too numerous and intricate to discuss here. For example, some investigators have suggested that presenting a patient with feedback actually interferes with relaxation, producing instead a state of heightened cognitive and physiological arousal (see, for example, the work of Brener, Lang, and Surwit). Another issue concerns the use of electromyographic feedback from the frontal (forehead) muscles to produce gen-

eralized relaxation; Surwit and Keefe (1978) contend that frontal EMG feedback has been used in a "physiologically naive manner." (For further discussion of this question see, in addition to Surwit and Keefe, Stoyva's work, and Gatchel et al. 1978). Other issues concerning relaxation and biofeedback are discussed in articles by Davidson and Schwartz (1976), Stroebel and Glueck (1978), Corby and associates (1978), as well as in the references noted above.

Transfer of Training

Beginning with the early work of Budzynski and Stoyva, many investigators have attempted to design treatment programs that would help patients continue to exercise control after they had completed biofeedback training and were once again facing stressful life situations. Until recently, most of these attempts have been limited to instructions to clients to continue relaxation exercises at home. As noted earlier, biofeedback training has been used primarily to *develop* skills; other behavioral strategies are available to help *maintain* them (Shapiro and Surwit 1976 and 1979). One example is the work of Holroyd and his colleagues (1979) discussed above.

According to Epstein and Blanchard (1977), maintaining control over a stress disorder such as tension headaches depends on these conditions:

- The subject must be able to tell when to begin control strategies such as relaxation exercises. "If he waits too long before beginning self-control then pain may be present, and the sustained muscle contraction associated with pain may be difficult to reduce." False alarms are equally troublesome. If the person believes a headache is coming on when tension is not present, the condition may become even worse, developing into a conversion reaction or a chronic pain problem.
- Headache patients must be able to detect when they have successfully reduced muscle tension, then give themselves some kind of reinforcement.

- The reinforcer itself should be appropriate to maintaining control over long periods. Just what that should be is still a matter of some question. Epstein and Blanchard believe that knowing when to reinforce is more important than the reward itself.

Lynn and Freedman (1979) have reviewed the research on helping patients transfer skills to everyday life. Among the strategies they think may be important are: overlearning the target response; booster sessions following treatment; gradually reducing ("fading") the feedback; controlling stimuli that precede a response; training under stressful conditions; and using self-control, self-management procedures (such as those suggested by Epstein and Blanchard).

Blood Pressure

Hypertension

As a serious public health problem afflicting 15 to 20 percent of the U.S. population, hypertension was the target of some of the earliest attempts to train human subjects to control autonomic functions. Most of the early work was done by psychologist David Shapiro and his colleagues at Harvard University (e.g., Shapiro et al. 1969). In order to register and feed back information on blood pressure, the Harvard researchers were compelled to design a new blood-pressure cuff that could measure blood pressure with each surge of blood produced by a heartbeat. Their "constant-cuff" device could be left on the patient's arm for a longer period than regular blood-pressure cuffs and could automatically monitor changes in either systolic or diastolic blood pressure. Even small changes could then be transformed into a signal fed back to the subject. This device has been used in most blood-pressure studies and has become commercially available.

Recent reviews on the use of biofeedback to control essential hypertension have been done by Seer (1979), Blanchard (1979), Ray et al. 1979, Frumkin et al. (1978), and A.P. Shapiro et al. (1977). These reviewers agree that, with one or two exceptions, most biofeedback training for control of hyper-

tension has proven disappointing. As A.P. Shapiro's group and Seer note, current evidence supports the use of biofeedback and relaxation techniques as *adjuncts*, rather than as *alternatives*, to standard medical treatment. Only one study using blood-pressure feedback has shown clinically significant decreases in blood pressure after an adequate period of followup, according to Blanchard (1979). In that study, Kristt and Engel (1975) used biofeedback to train their patients to lower blood pressure, taught them to monitor their own blood pressure, and told them to practice at home. "The regular utilization of these self-management skills is probably responsible for the good follow-up results and is a policy which should certainly be instituted on a clinical basis," concludes Blanchard. Kristt and Engel remain the only investigators to report data on the transfer of biofeedback training effects to the natural, although not necessarily stressful, environment.

An English investigator, Chandra Patel, and her associates, in what Blanchard calls "one of the most outstanding sets of studies in the whole field of clinical biofeedback," train their patients in a combination of skills—relaxation and meditation, enhanced by feedback of both muscle tension and skin conductivity. Patel's studies (e.g., Patel 1977 and Patel and North 1975) have not been carefully controlled for nonspecific effects, but followup has shown that gains obtained during treatment have been maintained. Concludes Blanchard:

> It would certainly seem that Patel has developed a "treatment package" which has very beneficial effects on hypertensive patients. Whether biofeedback plays any important role in their treatment is not known. Personal communication from Patel indicates that the biofeedback is a minor part of the treatment and that the passive relaxation training and meditation are probably the more important aspects. [Blanchard 1979, p. 40]

All in all, psychological treatment for high blood pressure seems to offer some promise, but only as a supplement to drug treatment. Biofeedback helps some patients relax; and it

is relaxation that may be responsible for the treatment effect. No evidence is available on which patients might do better with feedback than without it.

Blanchard observes that a consistent finding reported in the research literature is the need for patients to continue regular, almost daily, practice if the benefits of psychological treatments are to be maintained. This presents a problem. Patients are notoriously prone to forget to take medications for hypertension, presumably because the condition itself is without symptoms and because the medication produces undesirable side effects. While psychological treatments do not produce comparable side effects, they do take time and effort, which may be too much for patients who do not feel sick.

Patel attributes some of the success she has achieved to group meetings held with patients before biofeedback and relaxation training begin. At the meetings, patients discuss their problems, the disorder for which they are being treated, the relationship between emotional and physiological functioning, and the treatment procedure itself (Lynn and Freedman 1979).

Hypotension

Abnormally low blood pressure, although much less common than high blood pressure, can be a serious condition. Blood cannot reach the brain when the person with very low blood pressure is standing. Of the few cases treated with biofeedback, most have been reported by Miller's group with patients at New York's Goldwater Memorial Hospital.

The study team got involved by chance in one of those interesting instances in which researchers owe as much to a patient as he to them. Miller (1979) tells this story: A patient whose spinal cord had been severed by a gunshot wound begged Miller's collaborator, Bernard Brucker, to train him to increase his blood pressure. The man had been persistently trying to walk with the aid of crutches and braces for 3 years; these efforts had failed because he fainted every time he was in an upright position. The physical therapists had given up, but the patient had not. He had heard that Brucker was involved in attempts to lower blood pressure using biofeedback. Because those attempts had produced only small changes,

and because the man was so seriously injured, the researchers felt that the prospect of success was "dim indeed."

The patient surprised them. "Perhaps because he could produce large, prompt increases, this patient became able to perceive them, which enabled him to practice by himself," Miller notes. The man's ability to produce these changes on request "conclusively demonstrated specific voluntary control and could scarcely have been a placebo effect." The man was able to learn to walk with crutches and braces because of this control. Four years after training he was still doing it and was living in his own apartment (Brucker and Ince 1977).

Brucker (1977) went on to study 10 other patients with similar handicaps. Of the nine who learned to raise their blood pressure appreciably, two suffered from extreme postural hypotension. Both learned to raise their blood pressure sufficiently to sit up, their legs down, without fainting.

Cardiac Arrhythmias

As noted earlier, studies on heart-rate control have dominated the search for the behavioral or physiological mechanisms involved in biofeedback. Clinical application of this skill has been scant, however. Much of the work has been done by Bernard Engel and his colleagues, notably Theodore Weiss, at The Johns Hopkins University Hospital in Baltimore. Most studies involve cardiac arrhythmias—abnormality in the rate of the heartbeat or the impulses generating it. Cardiologists believe that many of these abnormalities are harmless. Other arrhythmias follow or precede heart attacks, and at least one is associated with sudden death. Slowing or speeding the heart can, in some, produce a more regular rhythm.

One of the arrhythmias which Engel (1977) considers cardiologically insignificant is sinus tachycardia, which the patient experiences as a rapidly pounding heart. In the absence of other cardiac disease, it is considered a psychiatric problem. Sinus tachycardia is the only cardiac arrhythmia for which the treatment efficacy of biofeedback has been systematically evaluated. Biofeedback has been assessed systematically in case studies of patients with other arrhythmias;

however, the goal in these studies was to study whether feedback could affect cardiac functioning or to clarify basic mechanisms, not to evaluate the merits of biofeedback in treating the conditions.

Recent reviews of this literature include those by Engel (1977 and 1979), Blanchard (1979), and Ray et al. (1978). There is virtually no disagreement among them. Biofeedback is seen as promising but unproven. Patients with tachycardias have often felt less anxious and more in control of themselves after biofeedback training. Ray and colleagues (1979) suggest that patients with these disorders may be particularly suited to biofeedback training.

Premature ventricular contractions, a serious condition associated with sudden death, has been studied in several laboratories. Blanchard says that the best studies, by far, have been done by Engel's group (see, for example, Engel 1972, 1973, and 1979, and Engel and Bleecker 1974). These systematic case studies remain exemplary among all biofeedback studies because patients were given instructions in home practice, which helped them to transfer to everyday life the control they had learned as hospital inpatients.

Other arrhythmias treated by biofeedback have similarly shown enough improvement to lead reviewers to suggest further clinical trials. This research, although some of the oldest in the biofeedback literature, has so far produced little of value to patients with cardiovascular problems. It has, however, as Engel has pointed out, brought together groups of scientists who have never worked together before. If they collaborate as Engel (1977) predicts, the resulting studies should clarify the therapeutic role of biofeedback for cardiovascular patients.

Raynaud's Disease

Although not life-threatening, Raynaud's disease is one of the most annoying of the cardiovascular disorders. An attack of Raynaud's, which is brought on by exposure to cold or emotional stress, may occur several times a day during cold weather. Discomfort is caused by constriction of the blood

vessels in the extremities. Fingers and, in some cases, toes turn white, then blue, and feel cold and numb. When the hands or feet are warmed, the vessels dilate and blood rushes back, producing throbbing pain, swelling, and redness. Skin temperature, a rough indicator of blood flow, falls and rises with the sensations of cold and warmth.

Conventional medical treatments of Raynaud's disease (drugs, surgery, instructions to avoid cold) seldom provide more than partial relief and may produce unwanted side effects. Even the drastic step of severing sympathetic nerves prevents further attacks in only 50 percent of patients. By contrast, behavioral treatments are benign. And they have shown sufficient promise to lead many clinicians to consider them the treatment of choice for Raynaud's disease.

Autogenic training, which specifically directs patients to imagine their hands growing heavy and warm, has been used for decades in the treatment of Raynaud's symptoms. It or another relaxation technique is usually part of biofeedback treatment strategies. Skin temperature from the back of a finger is typically used as feedback.

Recent reviews of the literature on biofeedback treatment of Raynaud's disease have been done by a Biofeedback Society of America task force (Taub and Stroebel 1978), Ray's group (1979), and Sappington and his associates (1979). While acknowledging that the research evidence is far too skimpy to draw firm conclusions, reviewers agree that, when accompanied by relaxation training, biofeedback has been effective in relieving the frequency and severity of Raynaud's attacks. However, until recently, most studies have been poorly controlled and have involved only a few cases. The mechanism responsible for improvement is also unclear; as with many other biofeedback applications, relaxation (rather than control learned with feedback) may prove to be responsible for treatment gains.

Raynaud's disease has received a good deal of attention in the biofeedback literature for several reasons: First, research has amply demonstrated that hand temperature can be raised or lowered after biofeedback training. Second, procedures are relatively uncomplicated because temperature changes can be

measured accurately—even at home—with simple, inexpensive devices. Raynaud's disease also lends itself to voluntary control. Since the symptoms are episodic, as Taub and Stroebel point out, self-regulation needs to be exerted only long enough to prevent or stop an attack; chronic conditions such as high blood pressure, by contrast, require continuous regulation. Furthermore, the "relative neurological simplicity of Raynaud's disease makes it a model cardiovascular disorder on which to test the efficacy of a behavioral intervention" (Surwit et al. 1978).

Surwit and his colleagues at Duke and Harvard Universities have recently attempted to clarify whether and why biofeedback strategies produce relief from Raynaud's disease. Issues they have addressed include:

- The relative contributions of relaxation and skin-temperature feedback in achieving control.
- Individual differences in response to treatment.
- The value of laboratory training versus home training.
- Generalization of the ability to control finger temperature in the absence of feedback or taped instructions.
- The value of outcome measures—self-reports versus laboratory measures of physiological response to stressful cold.
- Long-term maintenance of control and how it is achieved.

In one of the first group-outcome studies of biofeedback for Raynaud's, Surwit's group found that skin-temperature feedback did *not* add to the benefits achieved from autogenic training alone (Surwit et al. 1978). All groups of subjects reported fewer and less severe attacks after they had gone through treatment. Those who were trained in the laboratory (two sessions a week for 6 weeks) did no better than those who were only given instructions for home training (three half-hour sessions)—evidence that the treatment results were not attributable to placebo factors.

Differences were found among individuals who took part in the study, however. Those who scored low on a test measure of "alienation" did much better at regulating hand temperature than those who scored high (Surwit et al. 1979). Because a high alienation score is associated with a defeatist attitude, Surwit and his colleagues suggest that poor motivation may have reduced compliance with the treatment program and undercut its effectiveness.

Of the original 30 patients, 19 took part in a followup study 1 year after treatment (Keefe et al. 1979). Although they reported improvement in their symptoms, the subjects had lost their ability to maintain finger skin temperatures when subjected to cold in the laboratory. Again, failure to continue practicing probably accounts for the loss of control, according to the researchers.

A second study by the same group confirmed the results of the first (Keefe et al. 1980). However, it also suggested that feedback may serve some purpose in the treatment of Raynaud's disease. First, the physiological monitoring itself may be useful, because it offers clinicians data from which to assess improvement. Second, as Keefe and colleagues point out, some individuals may have benefited from the biofeedback training, but their results would have been buried in the group averages.

Another benefit of biofeedback was suggested by a third study (Surwit and Fenton 1980). Although feedback did not improve the subjects' ability to *develop* control over finger temperature, it did help them to *maintain* the control once it had been established. Surwit and Fenton argue that feedback acted as a reinforcer to maintain voluntary changes begun with the help of instruction.

The research of Surwit and his co-workers is one example of the attempts of scientists to isolate the effective components in a treatment package and to refine clinical strategies at the same time. The findings suggest, for example, that groups of patients can be instructed by a therapist during a few sessions, then go home and practice with tape-recorded instructions—certainly an inexpensive form of treatment. However, the failure of subjects to maintain control after a

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year underscores an observation that has been made several times in the last few years: Behavioral techniques must be practiced regularly to be effective. As the researchers note, a therapist must do more than simply instruct a patient to continue practicing. They suggest that attention should now be directed at devising strategies to assure that patients comply with instructions. Because both disease mechanisms and treatment methods are less complex in Raynaud's than in most other psychophysiological disorders, this line of research may produce leads for future work on more common, more lethal disorders.

Alpha Rhythms

Alpha is not a disease but a brainwave frequency. Much of the popular interest in biofeedback, as Beatty (1977a and b) and others have noted, can be attributed to the early research on alpha. Beatty describes the alpha rhythm as characterized by high-amplitude, low-frequency (8 to 13 cycles per second) waveforms, easily observed in the electroencephalogram (EEG) of awake subjects, which cluster together to form bursts of activity contrasting sharply with the fast, low-amplitude activity that precedes and follows alpha. On an EEG record, alpha waves look like mountains jutting up from flatlands and hill country. Alpha activity has something of the character of an "electroencephalographic event or state," as Beatty describes it. Recorded most often over the occipital region of the brain, where most visual processing is done, it usually occurs when a person is quiet, relaxed, and drowsy.

The early studies by Kamiya (1969) and Brown (1970) attempted to train subjects to achieve this state through feedback methods. Reviews of this research have concluded that "large amounts of alpha frequency activity do not correspond to a special state of subjective experience" (Beatty 1977a).

Martin Orne and his co-workers at the University of Pennsylvania have concluded that there is no real physiological significance to alpha (Orne and Wilson 1978). Their subjects were allowed to adjust to sitting in a darkened room with their eyes closed before they were given alpha feedback. EEG

records showed that the subjects produced alpha rhythms at levels that were as high before feedback started as they were after alpha signals were fed back. Orne concludes that the relaxed state produced in alpha training is achieved by learning to ignore stimuli that usually inhibit alpha—in Orne's terminology, by learning to "disinhibit" alpha.

Seizure Disorders

One critic of the alpha feedback experiments (Johnson 1977) contends that EEG feedback training has not even been demonstrated. In their recent review of clinical applications of EEG feedback, Kuhlman and Kaplan (1979) argue that, if Johnson is correct, then therapeutic strategies contingent upon learning EEG changes are questionable. Patients with epilepsy and other seizure disorders have responded to biofeedback training of the EEG, however. M.H. Sterman and his colleagues at the Sepulveda (Calif.) Veterans Administration Hospital, starting with experiments with cats, pioneered in this field (see, for example, Sterman 1973).

According to Kuhlman and Kaplan, most clinical research attempted to enhance particular EEG frequencies recorded from the central area of the scalp overlying the sensorimotor area of the cerebral cortex. In four of Sterman's patients, seizure rates declined by an average of 66 percent. When training was interrupted for extended periods, the rate of seizures rose to pretraining levels in 4 to 6 weeks. Kuhlman and Kaplan argue that these relapses do not prove that the biofeedback was producing the therapeutic effect. Removing the patient from the treatment setting, they explain, also removes many variables which might exert placebo effects.

Following Sterman's efforts, other investigators attempted to replicate his findings. Some succeeded, others did not. Kuhlman refined the procedures to control for placebo effects. In a small controlled study of five epileptic patients, he was able to discount the role of placebo, relaxation, sensory stimulation, and changes in anticonvulsant medication. Even under these strict conditions, clinically significant reductions in seizures were obtained.

Kuhlman and Kaplan argue that seizures are reduced through a process of "normalization"—that is, the epileptic patient's brain comes to resemble a non-epileptic's. They report that this explanation of the mechanism by which EEG feedback reduces seizures is becoming increasingly accepted: "There now appears to be a consensus that EEG normalization rather than selective enhancement of any specific frequency range of EEG activity is most clearly associated with reduced seizures."

Biofeedback treatment has resulted in impressive clinical improvement of epileptic patients, most of whom had not responded previously to medication. Seizures were typically cut in half in more than 50 percent of the patients in studies that controlled for nonspecific factors, report Kuhlman and Kaplan. The improvement also transferred to nontraining days in nearly all of these studies.

In addition to the Kuhlman and Kaplan article, other recent reviews of biofeedback treatment of epilepsy have been done by Ray et al. (1979) and Sterman (1977).

Gastrointestinal Disorders

Disorders of the gastrointestinal tract have only recently been treated with biofeedback techniques. The procedure has shown promise, particularly in the treatment of incontinence of the bowel. Techniques for this group of disorders are among the most unusual in the whole field of biofeedback.

Recent reviews on the subject have been done by a Biofeedback Society of America task force (Whitehead 1978) and Ray and associates (1979), among others. Whitehead's task force report notes that the following have been treated with biofeedback: Disorders of salivation and gastric acid and bile secretion, as well as motor functions such as rumination, esophageal and anal sphincter contractions, and gastric acid and colonic motility. The task force concludes that there is "suggestive evidence" that EMG biofeedback for muscle relaxation may aid in the healing of peptic ulcers as well. This evidence is even less advanced than that for the other gastrointestinal disorders, however.

Attention has recently focused on a particularly troublesome disorder, fecal incontinence, because it has resisted other types of treatment except surgery. Engel, Nikoomanesh, and Schuster (1974) developed a procedure for retraining sphincter control. A balloon was inflated in the rectum to stimulate the internal sphincter to relax and the external sphincter to contract—to simulate the movement of stool. Watching a record of the sphincter response, the patient was praised for each improvement in approximating the desired response. Several investigators have tried the technique with a few patients. Although none of these studies was well controlled, the technique is now considered the treatment of choice for sphincter impairment, according to Whitehead. Ray's group also concludes that this and other gastrointestinal disorders might benefit from biofeedback but does not endorse the technique quite so heartily. These reviewers point out that the comparatively short time and low cost of administering biofeedback for gastrointestinal disorders make it worth trying.

Psychological Symptoms

Recent alarming reports about the overuse and abuse of psychoactive drugs, especially in the treatment of anxiety, have intensified the search for an alternative. Biofeedback has been used to aid relaxation in the treatment of anxiety, insomnia, addictions, and other disorders most likely to be seen in a mental health setting. Stroebel (1979) notes that biofeedback can also be used as an adjunct to refine more traditional therapeutic approaches. The technique, Stroebel points out, provides a "real-time psychological mirror," and as such may sensitize both patient and therapist to the patient's reactions during therapy. Others (e.g., Legalos 1973) have reported that biofeedback may help patients to acknowledge their need for psychotherapy.

Lang (1977), after reviewing basic research on heart-rate control, concludes that biofeedback should not be used as a routine treatment for anxiety. He suggests that it may, instead, serve a monitoring function, allowing the therapist to provide

the patient with periodic "scoreboards" of therapeutic progress.

Recent reviews of the literature on clinical biofeedback training for psychological and psychiatric disorders have been done by Ray and his colleagues (1979), Gatchel (1979), and a task force of the Biofeedback Society of America (Rickles et al. unpublished). Fotopoulos and Sunderland (1978), in another BSA task force report, summarize the recent findings on psychophysiological disorders such as stuttering and urinary incontinence, as well as sexual disorders. In addition, general discussions of strategies involved in general psychiatry and psychosomatic medicine have been done by Adler and Morrissey-Adler (1979a and b).

According to Gatchel, there are no adequate assessments of the value of biofeedback in treating fear and anxiety. The BSA task force and Ray's group agree with this evaluation, adding that the same is true of the treatment of insomnia. Relatively more research has been done on the addictions, with mixed results (Rickles et al.). Controlled studies suggest that biofeedback does not improve the effectiveness of systematic desensitization in the treatment of phobias.

Recently, reports have begun to appear about the use of biofeedback in the treatment of tardive dyskinesia, a movement disorder associated with long-term use of some antipsychotic drugs. The anecdotal case reports (e.g., Albanese and Gaarder 1977 and Frederiksen and Rosenbaum 1979) have been positive, but better controlled research is needed.

Neuromuscular Disorders

Without question, the most widely accepted use of biofeedback is for the movement disorders. Usually done with electromyographic (EMG) feedback, the training is considered an adjunct to other procedures used in the rehabilitation of patients suffering from disabilities associated with neuromuscular disease. To use biofeedback, according to Fernando and Basmajian (1978), "one should be well versed in many other applied sciences, including electromyography, pathology, neurology, kinesiology, and muscle reeducation." Depending on the disorder, the techniques are directed at inhibiting spasti-

city, activating neuromuscular cells, and relaxing muscles (Fernando and Basmajian 1978).

The leader in this field is John Basmajian, now Director of the Rehabilitation Centre at Chedoke Hospitals in Hamilton, Ontario, Canada. It was Basmajian who, in the early 1960s, demonstrated that paralyzed patients could activate single motor-cell units (Basmajian 1977). Such fine control had previously been thought impossible. Biofeedback training is used to help patients recognize and develop neuromuscular units that remain viable despite the paralysis.

Recent reviews of the neuromuscular literature include Fernando and Basmajian's 1978 report for a task force of the Biofeedback Society of America and articles by Ray's group (1979); Keefe and Surwit (1978); Engel-Sittenfeld (1977); Cleeland (1979); and Basmajian and Hatch (1979). Most of these recent surveys support biofeedback's effectiveness—most with enthusiasm, some with reservations. On the positive side is the BSA task force, which concluded, for example, that EMG treatment for hemiplegia (paralysis of one side of the body) "is no longer to be considered as an experimental mode" (Fernando and Basmajian 1978). Reservations are expressed by Keefe and Surwit (1978), who believe that new studies of biofeedback treatment for hemiplegia and other neuromuscular disorders must be more methodologically sophisticated if one is to conclude that the procedure makes a unique contribution.

Even these critics acknowledge, however, that in the treatment of hemiplegia the results "are impressive in view of the fact that virtually all patients in these studies had failed to respond to conventional forms of physical therapy." Most patients had lived with their disorder for several years before they were treated with biofeedback. As Keefe and Surwit go on to conclude, "EMG feedback may be useful in a comprehensive program of neuromuscular reeducation for some stroke victims."

Hemiplegia is most often caused by a stroke. Among the best assessments of biofeedback retraining for stroke victims is a study done by Basmajian and his associates (1975). That study, according to Keefe and Surwit, is the only group-out-

come study to compare biofeedback training with conventional physical therapy. The results showed that patients who received physical exercise and biofeedback improved twice as much as those who received physical therapy. Although it has been criticized on several technical points, the research done by Basmajian's group remains a "benchmark study" in assessing biofeedback training for stroke victims (Ray et al. 1979).

Ray's group, despite reservations about the methodological problems in treatment assessment studies, says that the technique is both effective and economical (especially when standard EMG monitoring equipment is used).

> In nearly every study patients have shown functional or cosmetic improvements that are generally well maintained. Further, in most cases the improvements have come about in a shorter timespan and with less therapist contact than would be necessary for the completion of traditional physical therapeutic rehabilitation. [Ray et al. 1979, p. 80]

Engel-Sittenfeld (1977) essentially agrees with this assessment and goes on to point out that functional improvement differs widely from patient to patient, as does the training time required. Most reviewers note that being able to produce *any* movement in the extremities can give patients a huge psychological boost, especially if they have been paralyzed for several years.

Cerebral palsy (CP) has also been treated with EMG and other types of feedback. In cerebral palsy patients, feedback training is usually used to improve posture and gait and alleviate spastic movements. Fernando and Basmajian (1978) conclude that this use is promising, but they point out that evidence of the feedback's contribution to improvement is lacking. "However," they say, "many CP studies employ quantitative measures, statistical analysis of results, and a level of experimental sophistication that is well above that of most studies of biofeedback related to physical medicine and rehabilitation." Among the best studies in this area is that done by Finley and his associates (1977).

Several disorders characterized by spasmodic movements have been treated with biofeedback, but the evidence to date is too scarce for reviewers to conclude whether the feedback provided any benefits above and beyond other aspects of the treatment. However, biofeedback is seen as a promising alternative to usual treatment procedures (e.g., surgery), which are more drastic, costly, and time-consuming. Of the several psychophysiological disorders reviewed by Fotopoulos and Sunderland (1978) in a BSA task force report, only spasmodic torticollis (an involuntary movement of the head toward the shoulder) has been shown to respond to biofeedback in a large number of patients, although group-outcome studies have not been done.

Chronic pain caused by muscle spasms, such as some types of chronic low-back pain, has been treated with EMG feedback and relaxation training, but surprisingly little has been reported about the effectiveness of this procedure.

Other neuromuscular disorders that have been treated with biofeedback include polio, Parkinson's disease, nerve injury, jaw-clenching, and tooth-grinding. Although still inadequate, the research on biofeedback training has, according to Fernando and Basmajian, "provided a major impetus for the advance of our body of knowledge for treating neurological dysfunctions." Regardless of its eventual usefulness, however, biofeedback has brought hope to patients afflicted with conditions that once seemed immutable. These two authors conclude:

> Against a background where no effective means exist for the treatment of movement disorders—drugs, surgical methods, or physical medicine and rehabilitation techniques—biofeedback offers new hope but no miracles. [Fernando and Basmajian 1978, p. 448]

The probability that biofeedback will ultimately prove most useful for treating neuromuscular disorders is not surprising, since the functions that have gone awry are mediated by the central nervous system and are normally under volun-

tary control. Training patients to gain or regain that control is partly a matter of assisting them to recognize and regulate faint signals from damaged tissue. The procedure involves learning a skill, under conditions where the feedback signals that usually guide the learning are muted. Here, machines can make a difference.

5

LOOKING TO THE FUTURE

The case for the clinical effectiveness of biofeedback is still open. Careful scrutiny has failed to substantiate the extreme early claims for its therapeutic potency. However, biofeedback has uncovered new possibilities, if not of complete control, then at least of some influence over maladies and mechanisms which Western societies had traditionally considered immune to conscious manipulation. Even the strongest critics of research on the therapeutic effectiveness of biofeedback do not want to see the technique abandoned. They just want it demystified.

Following a 1976 international conference, Beatty and Legewie (1977) summed up the field in these words: "Biofeedback. . .may play some part in the study of man and in the treatment of human disorders. That part may not be large, but in selected areas it may be important."

For most disorders, further clinical research is needed before biofeedback can be ruled either in or out as an effective, efficient therapeutic technique. In the treatment of tension headache, high blood pressure, and other stress-related disor-

ders, the evidence is mounting that biofeedback adds little to the benefits of meditation or relaxation techniques, which are cheaper and easier to carry out in daily life. By contrast, feedback of muscle activity has shown great promise in the treatment of many neuromuscular disorders. Biofeedback may yet prove useful in controlling stress disorders also. It might, for instance, help some individuals learn to recognize how it feels to be relaxed. For others, simply monitoring the effects of emotions, thoughts, and events on physiological responses may provide the impetus to change what needs to be—and can be—changed in their day-to-day lives.

Because so little is understood about the behavioral and physiological mechanisms involved when biofeedback does enhance voluntary control, the procedures used to date are probably far from perfected. Thus, biofeedback might be more effective clinically if its technology were improved. For example, Garcia and Rusiniak (1974) have argued that feedback signals used in most biofeedback procedures have been too neutral. They suggest using feedback with greater "hedonic value"—in other words, reinforcements that would give more pleasure to the learner. Such refinements could improve both the magnitude and duration of change. Especially important are techniques that induce biofeedback graduates to continue practicing skills acquired during training.

Beyond the task of strengthening the clinical applications of biofeedback, researchers of the future have numerous other challenges: determining how biofeedback works—when it works; comparing it to alternate treatments for specific disorders; weighing its costs and benefits to the patient and the community; and judging its safety. Until this knowledge accumulates, biofeedback should be regarded—as should most treatments for mental and physical disorders—with cautious optimism.

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